103D CONGRESS
1ST SESSION

S. 1

AN ACT

To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.

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To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''National Institutes of Health Revitalization Act of 1993''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

TITLE I—GENERAL PROVISIONS REGARDING TITLE IV OF PUBLIC HEALTH SERVICE ACT

Subtitle A—Research Freedom

PART I—REVIEW OF PROPOSALS FOR BIOMEDICAL AND BEHAVIORAL RESEARCH

SEC. 101. ESTABLISHMENT OF CERTAIN PROVISIONS REGARDING RESEARCH CONDUCTED OR SUPPORTED BY NATIONAL INSTITUTES OF HEALTH.

Part G of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 492 the following new section:

''CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL OF PROPOSALS FOR RESEARCH

''SEC. 492A. (a) REVIEW AS PRECONDITION TO RESEARCH.—

''(1) PROTECTION OF HUMAN RESEARCH SUBJECTS.—

''(A) In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to review under section 491(a) by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

''(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.

''(2) PEER REVIEW.—In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to technical and scientific peer review under section 492(a) unless the application has undergone peer review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review.

''(b) ETHICAL REVIEW OF RESEARCH.—

''(1) PROCEDURES REGARDING WITHHOLDING OF FUNDS.—If research has been recommended for approval for purposes of subsection (a), the Secretary may not withhold funding for the research on ethical grounds unless—

''(A) the Secretary convenes an advisory board in accordance with paragraph (4) to study the ethical implications of the research; and

''(B)(i) the majority of the advisory board recommends that, on ethical grounds, the Secretary withhold funds for the research; or

''(ii) the majority of such board recommends that the Secretary not withhold funds for the research on ethical grounds, but the

Secretary finds, on the basis of the report submitted under paragraph (4)(B)(ii), that there is a reasonable basis for overruling the board's recommendations.

''(2) APPLICABILITY.—The limitation established in paragraph (1) regarding the authority to withhold funds on ethical grounds shall apply without regard to whether the withholding such funds is characterized as a disapproval, a moratorium, a prohibition, or other description.

''(3) PRELIMINARY MATTERS REGARDING USE OF PROCEDURES.—

''(A) If the Secretary makes a determination that an advisory board should be convened for purposes of paragraph (1), the Secretary shall, through a statement published in the Federal Register, announce the intention of the Secretary to convene such a board.

''(B) A statement issued under subparagraph (A) shall include a request that interested individuals submit to the Secretary recommendations specifying the particular individuals who should be appointed to the advisory board involved. The President shall consider

such recommendations in making appointments to the board.

''(C) The President may not make appointments to an advisory board under paragraph (1) until the expiration of the 30-day period beginning on the date on which the statement required in subparagraph (A) is made with respect to the board.

''(4) ETHICS ADVISORY BOARDS.—

''(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (hereafter in this paragraph referred to as an 'ethics board').

''(B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of biomedical or behavioral research with respect to which the board has been convened.

''(ii) Not later than 180 days after the date on which the statement required in paragraph (3)(A) is made with respect to an ethics board, the board shall submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of

the Senate, a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. The report shall include the information considered in making the findings.

''(C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The President shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—

''(i) no fewer than 1 shall be an attorney;

''(ii) no fewer than 1 shall be an ethicist;

''(iii) no fewer than 1 shall be a practicing physician;

''(iv) no fewer than 1 shall be a theologian; and

''(v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.

''(D) The term of service as a member of an ethics board shall be for the life of the board. If such a member does not serve the full term of such service, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(E) A member of an ethics board shall be subject to removal from the board by the President for neglect of duty or malfeasance or for other good cause shown.

''(F) The President shall designate an individual from among the members of an ethics board to serve as the chair of the board.

''(G) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall conduct inquiries and hold public hearings.

''(H) With respect to information relevant to the duties described in subparagraph (B)(i), an ethics board shall have access to all such in-

formation possessed by the Department of Health and Human Services, or available to the Secretary from other agencies.

''(I) Members of an ethics board shall receive compensation for each day engaged in carrying out the duties of the board, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.

''(J) The Secretary, acting through the Director of the National Institutes of Health, shall provide to each ethics board such reasonable staff and assistance as may be necessary to carry out the duties of the board.

''(K) An ethics board shall terminate 30 days after the date on which the report required in subparagraph (B)(ii) is submitted to the Secretary and the congressional committees specified in such subparagraph.''.

PART II—RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

SEC. 111. ESTABLISHMENT OF AUTHORITIES.

Part G of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 498 the following new section:

''RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

''SEC. 498A. (a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

''(2) SOURCE OF TISSUE.—Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

''(b) INFORMED CONSENT OF DONOR.—

''(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the woman providing the tissue makes a statement, made in writing and signed by the woman, declaring that—

''(A) the woman donates the fetal tissue for use in research described in subsection (a);

''(B) the donation is made without any restriction regarding the identity of individuals

who may be the recipients of transplantations of the tissue; and

''(C) the woman has not been informed of the identity of any such individuals.

''(2) ADDITIONAL STATEMENT.—In research carried out under subsection (a), human fetal tissue may be used only if the attending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that—

''(A) in the case of tissue obtained pursuant to an induced abortion—

''(i) the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for the tissue to be used in such research; and

''(ii) no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue;

''(B) the tissue has been donated by the woman in accordance with paragraph (1); and

''(C) full disclosure has been provided to the woman with regard to—

''(i) such physician's interest, if any, in the research to be conducted with the tissue; and

''(ii) any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman's medical care.

''(c) INFORMED CONSENT OF RESEARCHER AND DONEE.—In research carried out under subsection (a), human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual—

''(1) is aware that—

''(A) the tissue is human fetal tissue;

''(B) the tissue may have been obtained pursuant to a spontaneous or induced abortion or subsequent to a stillbirth; and

''(C) the tissue was donated for research purposes;

''(2) has provided such information to other individuals with responsibilities regarding the research;

''(3) will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, written acknowledgment of receipt of such information by such recipient; and

''(4) has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of the research.

''(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—

''(1) IN GENERAL.—In research carried out under subsection (a), human fetal tissue may be used only if the head of the agency or other entity conducting the research involved certifies to the Secretary that the statements required under subsections (b)(1), (b)(2), and (c) will be available for audit by the Secretary.

''(2) CONFIDENTIALITY OF AUDIT.—Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect the privacy rights of the individuals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall—

''(A) use such material or information only for the purposes of verifying compliance with the requirements of this section;

''(B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and

''(C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

''(e) APPLICABILITY OF STATE AND LOCAL LAW.—

''(1) RESEARCH CONDUCTED BY RECIPIENTS OF ASSISTANCE.—The Secretary may not provide support for research under subsection (a) unless the applicant agrees to conduct the research in accordance with applicable State and local law.

''(2) RESEARCH CONDUCTED BY SECRETARY.—The Secretary may conduct research under subsection (a) only in accordance with applicable State and local law.

''(f) DEFINITION.—For purposes of this section, the term 'human fetal tissue' means tissue or cells obtained

from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.''.

SEC. 112. PURCHASE OF HUMAN FETAL TISSUE; SOLICITATION OR ACCEPTANCE OF TISSUE AS DIRECTED DONATION FOR USE IN TRANSPLANTATION.

Part G of title IV of the Public Health Service Act, as amended by section 111 of this Act, is amended by inserting after section 498A the following new section:

''PROHIBITIONS REGARDING HUMAN FETAL TISSUE

''SEC. 498B. (a) PURCHASE OF TISSUE.—It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

''(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS DIRECTED DONATION FOR USE IN TRANSPLANTATION.—It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and—

''(1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;

''(2) the donated tissue will be transplanted into a relative of the donating individual; or

''(3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

''(c) CRIMINAL PENALTIES FOR VIOLATIONS.—

''(1) IN GENERAL.—Any person who violates subsection (a) or (b) shall be fined in accordance with title 18, United States Code, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

''(2) PENALTIES APPLICABLE TO PERSONS RECEIVING CONSIDERATION.—With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

''(d) DEFINITIONS.—For purposes of this section:

''(1) The term 'human fetal tissue' has the meaning given such term in section 498A(e).

''(2) The term 'interstate commerce' has the meaning given such term in section 201(b) of the Federal Food, Drug, and Cosmetic Act.

''(3) The term 'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.''.

SEC. 113. REPORT BY GENERAL ACCOUNTING OFFICE ON ADEQUACY OF REQUIREMENTS.

(a) IN GENERAL.—With respect to research on the transplantation of human fetal tissue for therapeutic purposes, the Comptroller General of the United States shall conduct an audit for the purpose of determining—

(1) whether and to what extent such research conducted or supported by the Secretary of Health and Human Services has been conducted in accordance with section 498A of the Public Health Service Act (as added by section 111 of this Act); and

(2) whether and to what extent there have been violations of section 498B of such Act (as added by section 112 of this Act).

(b) REPORT.—Not later than May 19, 1995, the Comptroller General of the United States shall complete the audit required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and

Human Resources of the Senate, a report describing the findings made pursuant to the audit.

PART III—MISCELLANEOUS REPEALS

SEC. 121. REPEALS.

(a) CERTAIN BIOMEDICAL ETHICS BOARD.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by striking part J.

(b) OTHER REPEALS.—Part G of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended—

(1) in section 498, by striking subsection (c); and

(2) by striking section 499; and

(3) by redesignating section 499A as section 499.

(c) NULLIFICATION OF CERTAIN REGULATION.—The provisions of section 204(d) of part 46 of title 45 of the Code of Federal Regulations (45 CFR 46.204(d)) shall not have any legal effect.

Subtitle B—Clinical Research Equity Regarding Women and Minorities

PART I—WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH

SEC. 131. REQUIREMENT OF INCLUSION IN RESEARCH.

Part G of title IV of the Public Health Service Act, as amended by section 101 of this Act, is amended by inserting after section 492A the following new section:

''INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

''SEC. 492B. (a) In conducting or supporting clinical research for purposes of this title, the Director of NIH shall, subject to subsection (b), ensure that—

''(1) women are included as subjects in each project of such research; and

''(2) members of minority groups are included as subjects in such research.

''(b) The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

''(1) is inappropriate with respect to the health of the subjects;

''(2) is inappropriate with respect to the purpose of the research; or

''(3) is inappropriate under such other circumstances as the Director of NIH may designate.

''(c) In the case of any project of clinical research in which women or members of minority groups will under subsection (a) be included as subjects in the research, the Director of NIH shall ensure that the project is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being tested in the research affect women or members of minority groups, as the case may be, differently than other subjects in the research.

''(d)(1) The Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall establish guidelines regarding—

''(A) the circumstances under which the inclusion of women and minorities in projects of clinical research is inappropriate for purposes of subsection (b);

''(B) the manner in which such projects are required to be designed and carried out for purposes of subsection (c), including a specification of the circumstances in which the requirement of such sub-

section does not apply on the basis of impracticability; and

''(C) the conduct of outreach programs for the recruitment of women and members of minority groups as subjects in such research.

''(2) The guidelines established under paragraph (1)—

''(A) may not provide that the cost of including women and minorities in clinical research is a permissible consideration regarding the circumstances described in subparagraph (A) of such paragraph; and

''(B) may provide that such circumstances include circumstances in which there are scientific reasons for believing that the variables proposed to be studied do not affect women or minorities differently than other subjects in the research.

''(3) The guidelines required in paragraph (1) shall be established and published in the Federal Register not later than 180 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.

''(4) For fiscal year 1994 and subsequent fiscal years, the Director of NIH may not provide funding for any project of clinical research to be conducted or supported

by any agency of the National Institutes of Health unless the project specifies the manner in which the research will comply with subsection (a).

''(e) The advisory council of each national research institute shall annually submit to the Director of NIH and the Director of the institute involved a report describing the manner in which the agency has complied with subsection (a).''.

SEC. 132. PEER REVIEW.

Section 492 of the Public Health Service Act (42 U.S.C. 289a) is amended by adding at the end the following new subsection:

''(c)(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposed project (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposed project regarding compliance with section 492B(a).

''(2) Paragraph (1) shall not apply to any proposed project for clinical research that, pursuant to subsection (b) of section 492B, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.''.

SEC. 133. APPLICABILITY TO CURRENT PROJECTS.

Section 492B of the Public Health Service Act, as added by section 131 of this Act, shall not apply with respect to projects of clinical research for which initial funding was provided prior to the date of the enactment of this Act. With respect to the inclusion of women and minorities as subjects in clinical research conducted or supported by the National Institutes of Health, any policies of the Secretary of Health and Human Services regarding such inclusion that are in effect on the day before the date of the enactment of this Act shall continue to apply to the projects referred to in the preceding sentence.

PART II—OFFICE OF RESEARCH ON WOMEN'S HEALTH

SEC. 141. ESTABLISHMENT.

(a) IN GENERAL.—Title IV of the Public Health Service Act, as amended by section 2 of Public Law 101–613, is amended—

(1) by redesignating section 486 as section 485A;

(2) by redesignating parts F through H as parts G through I, respectively; and

(3) by inserting after part E the following new part:

''PART F—RESEARCH ON WOMEN'S HEALTH

"SEC. 486. OFFICE OF RESEARCH ON WOMEN'S HEALTH.

''(a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Research on Women's Health (in this part referred to as the 'Office'). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

''(b) PURPOSE.—The Director of the Office shall—

''(1) identify projects of research on women's health that should be conducted or supported by the national research institutes;

''(2) identify multidisciplinary research relating to research on women's health that should be so conducted or supported;

''(3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;

''(4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);

''(5) encourage the conduct of such research by entities receiving funds from the national research institutes;

''(6) recommend an agenda for conducting and supporting such research;

''(7) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research;

''(8) assist in the administration of section 492B with respect to the inclusion of women as subjects in clinical research; and

''(9) prepare the report required in section 486B.

''(c) COORDINATING COMMITTEE.—

''(1) In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (hereafter in this subsection referred to as the 'Coordinating Committee').

''(2) The Coordinating Committee shall be composed of the Directors of the national research institutes (or the designees of the Directors) and other appropriate entities.

''(3) The Director of the Office shall serve as the chair of the Coordinating Committee.

''(4) With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

''(A) identifying the need for such research, and making an estimate each fiscal year

of the funds needed to adequately support the research;

''(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;

''(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;

''(D) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function; and

''(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.

''(d) ADVISORY COMMITTEE.—

''(1) In carrying out subsection (b), the Director of the Office shall establish an advisory committee to be known as the Advisory Committee on Re-

search on Women's Health (hereafter in this subsection referred to as the 'Advisory Committee').

''(2)(A) The Advisory Committee shall be composed of no fewer than 12, and not more than 18 individuals, who are not officers or employees of the Federal Government. The Director of the Office shall make appointments to the Advisory Committee from among physicians, practitioners, scientists, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on research on women's health. A majority of the members of the Advisory Committee shall be women.

''(B) Members of the Advisory Committee shall receive compensation for each day engaged in carrying out the duties of the Committee, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.

''(3) The Director of the Office shall serve as the chair of the Advisory Committee.

''(4) The Advisory Committee shall—

''(A) advise the Director of the Office on appropriate research activities to be undertaken

by the national research institutes with respect to—

''(i) research on women's health;

''(ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;

''(iii) research on gender differences in disease etiology, course, and treatment;

''(iv) research on obstetrical and gynecological health conditions, diseases, and treatments; and

''(v) research on women's health conditions which require a multidisciplinary approach;

''(B) report to the Director of the Office on such research;

''(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of the methodologies described in subsection (c)(4)(C) and recommendations on priorities in carrying out research described in subparagraph (A)); and

''(D) assist in monitoring compliance with section 492B regarding the inclusion of women in clinical research.

''(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding—

''(i) compliance with section 492B;

''(ii) the extent of expenditures made for research on women's health by the agencies of the National Institutes of Health; and

''(iii) the level of funding needed for such research.

''(B) The report required in subparagraph (A) shall be submitted to the Director of NIH for inclusion in the report required in section 403.

''(e) REPRESENTATION OF WOMEN AMONG RESEARCHERS.—The Secretary, acting through the Assistant Secretary for Personnel and in collaboration with the Director of the Office, shall determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.

''(f) DEFINITIONS.—For purposes of this part:

''(1) The term 'women's health conditions', with respect to women of all age, ethnic, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

''(A) unique to, more serious, or more prevalent in women;

''(B) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women; or

''(C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

''(2) The term 'research on women's health' means research on women's health conditions, including research on preventing such conditions.

"SEC. 486A. NATIONAL DATA SYSTEM AND CLEARINGHOUSE ON RESEARCH ON WOMEN'S HEALTH.

''(a) DATA SYSTEM.—

''(1) The Director of NIH, in consultation with the Director of the Office, shall establish a data system for the collection, storage, analysis, retrieval, and dissemination of information regarding research

on women's health that is conducted or supported by the national research institutes. Information from the data system shall be available through information systems available to health care professionals and providers, researchers, and members of the public.

''(2) The data system established under paragraph (1) shall include a registry of clinical trials of experimental treatments that have been developed for research on women's health. Such registry shall include information on subject eligibility criteria, sex, age, ethnicity or race, and the location of the trial site or sites. Principal investigators of such clinical trials shall provide this information to the registry within 30 days after it is available. Once a trial has been completed, the principal investigator shall provide the registry with information pertaining to the results, including potential toxicities or adverse effects associated with the experimental treatment or treatments evaluated.

''(b) CLEARINGHOUSE.—The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain, and operate a program to provide information on research

and prevention activities of the national research institutes that relate to research on women's health.

"SEC. 486B. BIENNIAL REPORT.

''(a) IN GENERAL.—With respect to research on women's health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report—

''(1) describing and evaluating the progress made during the preceding 2 fiscal years in research and treatment conducted or supported by the National Institutes of Health;

''(2) describing and analyzing the professional status of women physicians and scientists of such Institutes, including the identification of problems and barriers regarding advancements;

''(3) summarizing and analyzing expenditures made by the agencies of such Institutes (and by such Office) during the preceding 2 fiscal years; and

''(4) making such recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate.

''(b) INCLUSION IN BIENNIAL REPORT OF DIRECTOR OF NIH.—The Director of the Office shall submit each report prepared under subsection (a) to the Director of

NIH for inclusion in the report submitted to the President and the Congress under section 403.''.

(b) REQUIREMENT OF SUFFICIENT ALLOCATION OF RESOURCES OF INSTITUTES.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (10), by striking ''and'' after the semicolon at the end;

(2) in paragraph (11), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (11) the following new paragraph:

''(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women's health that are identified under section 486(b).''.

PART III—OFFICE OF RESEARCH ON MINORITY HEALTH

SEC. 151. ESTABLISHMENT.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following new section:

''OFFICE OF RESEARCH ON MINORITY HEALTH

''SEC. 403A. (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office

to be known as the Office of Research on Minority Health (in this section referred to as the 'Office'). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

''(b) PURPOSE.—The Director of the Office shall—

''(1) identify projects of research on minority health that should be conducted or supported by the national research institutes;

''(2) identify multidisciplinary research relating to research on minority health that should be so conducted or supported;

''(3) promote coordination and collaboration among entities conducting research identified under paragraph (1) or (2);

''(4) encourage the conduct of such research by entities receiving funds from the national research institutes;

''(5) recommend an agenda for conducting and supporting such research;

''(6) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research; and

''(7) assist in the administration of section 492B with respect to the inclusion of members of minority groups as subjects in clinical research.''.

Subtitle C—Scientific Integrity

SEC. 161. ESTABLISHMENT OF OFFICE OF SCIENTIFIC INTEGRITY.

(a) IN GENERAL.—Section 493 of the Public Health Service Act (42 U.S.C. 289b) is amended to read as follows:

''OFFICE OF SCIENTIFIC INTEGRITY

''SEC. 493. (a) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 90 days after the date of enactment of this section, the Secretary shall establish an office to be known as the Office of Scientific Integrity (hereafter referred to in this section as the 'Office'), which shall be established as an independent entity in the Department of Health and Human Services.

''(2) DIRECTOR.—The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of scientific misconduct. The Secretary shall carry out this section acting through the Director of the Office. The Director shall report to the Secretary.

''(b) EXISTENCE OF ADMINISTRATIVE PROCESSES AS CONDITION OF FUNDING FOR RESEARCH.—The Secretary

shall by regulation require that each entity that applies for a grant, contract, or cooperative agreement under this Act for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity—

''(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of scientific misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity; and

''(2) will report to the Director any investigation of alleged scientific misconduct in connection with projects for which funds have been made available under this Act that appears substantial.

''(c) PROCESS FOR RESPONSE OF DIRECTOR.—The Secretary shall establish by regulation a process to be followed by the Director for the prompt and appropriate—

''(1) response to information provided to the Director respecting scientific misconduct in connection with projects for which funds have been made available under this Act;

''(2) receipt of reports by the Director of such information from recipients of funds under this Act;

''(3) conduct of investigations, when appropriate; and

''(4) taking of other actions, including appropriate remedies, with respect to such misconduct.

''(d) MONITORING BY DIRECTOR.—The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

''(e) EFFECT ON PRESENT INVESTIGATIONS.—Nothing in this section shall affect investigations which have been or will be commenced prior to the promulgation of final regulations under this section.''.

(b) ESTABLISHMENT OF DEFINITION OF SCIENTIFIC MISCONDUCT.—Not later than 90 days after the date on which the report required under section 152(d) is submitted to the Secretary of Health and Human Services, such Secretary shall by regulation establish a definition for the term ''scientific misconduct'' for purposes of section 493 of the Public Health Service Act, as amended by subsection (a) of this section.

SEC. 162. COMMISSION ON SCIENTIFIC INTEGRITY.

(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a commission to be known as the Commission on Scientific Integrity (in this section referred to as the ''Commission'').

(b) DUTIES.—The Commission shall develop recommendations for the Secretary of Health and Human Services on the administration of section 493 of the Public Health Service Act (as amended and added by section 161 of this Act).

(c) COMPOSITION.—The Commission shall be composed of 12 members to be appointed by the Secretary of Health and Human Services from among individuals who are not officers or employees of the United States. Of the members appointed to the Commission—

(1) three shall be scientists with substantial accomplishments in biomedical or behavioral research;

(2) three shall be individuals with experience in investigating allegations of misconduct with respect to scientific research;

(3) three shall be representatives of institutions of higher education at which biomedical or behavioral research is conducted; and

(4) three shall be individuals who are not described in paragraphs (1), (2), or (3), at least one

of whom shall be an attorney and at least one of whom shall be an ethicist.

(d) COMPENSATION.—Members of the Commission shall receive compensation for each day engaged in carrying out the duties of the Commission, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.

(e) REPORT.—Not later than 120 days after the date of enactment of this section, the Commission shall prepare and submit to the Secretary of Health and Human Services, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report containing the recommendations developed under subsection (b).

SEC. 163. PROTECTION OF WHISTLEBLOWERS.

Section 493 of the Public Health Service Act, as amended by section 161 of this Act, is amended by adding at the end the following new subsection:

''(f) PROTECTION OF WHISTLEBLOWERS.—

''(1) IN GENERAL.—In the case of any entity required to establish administrative processes under subsection (b), the Secretary shall by regulation establish standards for preventing, and for responding

to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith—

''(A) made an allegation that the entity, its officials or agents, has engaged in or failed to adequately respond to an allegation of scientific misconduct; or

''(B) cooperated with an investigation of such an allegation.

''(2) MONITORING BY SECRETARY.—The Secretary shall establish by regulation procedures for the Director to monitor the implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

''(3) NONCOMPLIANCE.—The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in retaliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being

provided by the Secretary for such project, or other actions as appropriate.

''(4) FINAL RULE FOR REGULATIONS.—The Secretary shall issue a final rule for the regulations required in paragraph (1) not later than 180 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.

''(5) REQUIRED AGREEMENTS.—For any fiscal year beginning after the date on which the regulations required in paragraph (1) are issued, the Secretary may not provide a grant, cooperative agreement, or contract under this Act for biomedical or behavioral research unless the entity seeking such financial assistance agrees that the entity—

''(A) will maintain the procedures described in the regulations; and

''(B) will otherwise be subject to the regulations.''.

SEC. 164. REQUIREMENT OF REGULATIONS REGARDING PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST IN CERTAIN PROJECTS OF RESEARCH.

Part H of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 493 the following new section:

''PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST IN CERTAIN PROJECTS OF RESEARCH

''SEC. 493A. (a) ISSUANCE OF REGULATIONS.—

''(1) IN GENERAL.—The Secretary shall define by regulation, the specific circumstances that constitute the existence of a financial interest in a project on the part of an entity or individual that will, or may be reasonably expected to, create a bias in favor of obtaining results in such project that are consistent with such financial interest. Such definition shall apply uniformly to each entity or individual conducting a research project under this Act. In the case of any entity or individual receiving assistance from the Secretary for a project of research described in paragraph (2), the Secretary shall by regulation establish standards for responding to, including managing, reducing, or eliminating, the existence of such a financial interest. The entity may adopt individualized procedures for implementing the standards.

''(2) RELEVANT PROJECTS.—A project of research referred to in paragraph (1) is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or

treatment and for which such entity is receiving assistance from the Secretary.

''(3) IDENTIFYING AND REPORTING TO THE DIRECTOR.—The Secretary shall ensure that the standards established under paragraph (1) specify that as a condition of receiving assistance from the Secretary for the project involved, an entity described in such subsection is required—

''(A) to have in effect at the time the entity applies for the assistance and throughout the period during which the assistance is received, a process for identifying such financial interests as defined in paragraph (1) that exist regarding the project; and

''(B) to report to the Director such financial interest as defined in paragraph (1) identified by the entity and how any such financial interest identified by the entity will be managed or eliminated such that the project in question will be protected from bias that may stem from such financial interest.

''(4) MONITORING OF PROCESS.—The Secretary shall monitor the establishment and conduct of the process established by an entity pursuant to paragraph (1).

''(5) RESPONSE.—In any case in which the Secretary determines that an entity has failed to comply with paragraph (3) regarding a project of research described in paragraph (1), the Secretary—

''(A) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest as defined in paragraph (1) in each public presentation of the results of such project; and

''(B) may take such other actions as the Secretary determines to be appropriate.

''(6) DEFINITION.—As used in this section:

''(A) The term 'financial interest' includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

''(B) The term 'assistance', with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

''(b) FINAL RULE FOR REGULATIONS.—The Secretary shall issue a final rule for the regulations required in subsection (a) not later than 180 days after the date of the enactment of the National Institutes of Health Revitalization Act of 1993.''.

SEC. 165. EFFECTIVE DATES.

(a) IN GENERAL.—The amendments made by this subtitle shall become effective on the date that occurs 180 days after the date on which the final rule required under section 493(f)(4) of the Public Health Service Act, as amended by sections 161 and 163, is published in the Federal Register.

(b) AGREEMENTS AS A CONDITION OF FUNDING.—The requirements of subsection (f)(5) of section 493 of the Public Health Service Act, as amended by sections 161 and 163, with respect to agreements as a condition of funding shall not be effective in the case of projects of research for which initial funding under the Public Health Service Act was provided prior to the effective date described in subsection (a).

TITLE II—NATIONAL INSTITUTES OF HEALTH IN GENERAL

SEC. 201. HEALTH PROMOTION RESEARCH DISSEMINATION.

Section 402(f) of the Public Health Service Act (42 U.S.C. 282(f)) is amended by striking ''other public and private entities.'' and all that follows through the end and inserting ''other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

''(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs;

''(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities; and

''(3) annually prepare and submit to the Director of NIH a report concerning the prevention and dissemination activities undertaken by the Associate Director, including—

''(A) a summary of the Associate Director's review of existing dissemination policies and techniques together with a detailed statement concerning any modification or restructuring, or recommendations for modification or restructuring, of such policies and techniques; and

''(B) a detailed statement of the expenditures made for the prevention and dissemination activities reported on and the personnel used in connection with such activities.''.

SEC. 202. PROGRAMS FOR INCREASED SUPPORT REGARDING CERTAIN STATES AND RESEARCHERS.

Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by adding at the end the following new subsection:

''(g)(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Center for Research Resources, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

''(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

''(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may—

''(i) provide technical assistance to the entities involved, including technical assistance in the prepa-

ration of applications for obtaining funds from the national research institutes;

''(ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and

''(iii) assist the entities in implementing such plan.

''(2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as the principal researchers of such projects supported by the Director.''.

SEC. 203. CHILDREN'S VACCINE INITIATIVE.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following new section:

''CHILDREN'S VACCINE INITIATIVE

''SEC. 404. (a) DEVELOPMENT OF NEW VACCINES.—The Secretary, in consulation with the Director of the National Vaccine Program under title XXI and acting through the Directors of the National Institute for Allergy and Infectious Diseases, the National Institute for Child Health and Human Development, the National Institute for Aging, and other public and private programs, shall carry out activities, which shall be consistent with the global Children's Vaccine Initiative, to develop affordable new and improved vaccines to be used in the United

States and in the developing world that will increase the efficacy and efficiency of the prevention of infectious diseases. In carrying out such activities, the Secretary shall, to the extent practicable, develop and make available vaccines that require fewer contacts to deliver, that can be given early in life, that provide long lasting protection, that obviate refrigeration, needles and syringes, and that protect against a larger number of diseases.

''(b) REPORT.—In the report required in section 2104, the Secretary, acting through the Director of the National Vaccine Program under title XXI, shall include information with respect to activities and the progress made in implementing the provisions of this section and achieving its goals.

''(c) AUTHORIZATION OF APPROPRIATIONS.—In addition to any other amounts authorized to be appropriated for activities of the type described in this section, there are authorized to be appropriated to carry out this section $20,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 204. PLAN FOR USE OF ANIMALS IN RESEARCH.

(a) IN GENERAL.—Part A of title IV of the Public Health Service Act, as amended by section 203 of this Act, is amended by adding at the end the following new section:

''PLAN FOR USE OF ANIMALS IN RESEARCH

''SEC. 404A. (a) The Director of NIH, after consultation with the committee established under subsection (e), shall prepare a plan—

''(1) for the National Institutes of Health to conduct or support research into—

''(A) methods of biomedical research and experimentation that do not require the use of animals;

''(B) methods of such research and experimentation that reduce the number of animals used in such research; and

''(C) methods of such research and experimentation that produce less pain and distress in such animals;

''(2) for establishing the validity and reliability of the methods described in paragraph (1);

''(3) for encouraging the acceptance by the scientific community of such methods that have been found to be valid and reliable; and

''(4) for training scientists in the use of such methods that have been found to be valid and reliable.

''(b) Not later than October 1, 1993, the Director of NIH shall submit to the Committee on Energy and

Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, the plan required in subsection (a) and shall begin implementation of the plan.

''(c) The Director of NIH shall periodically review, and as appropriate, make revisions in the plan required under subsection (a). A description of any revision made in the plan shall be included in the first biennial report under section 403 that is submitted after the revision is made.

''(d) The Director of NIH shall take such actions as may be appropriate to convey to scientists and others who use animals in biomedical or behavioral research or experimentation information respecting the methods found to be valid and reliable under subsection (a)(2).

''(e)(1) The Director of NIH shall establish within the National Institutes of Health a committee to be known as the Interagency Coordinating Committee on the Use of Animals in Research (hereafter in this subsection referred to as the 'Committee').

''(2) The Committee shall provide advice to the Director of NIH on the preparation of the plan required in subsection (a).

''(3) The Committee shall be composed of—

''(A) the Directors of each of the national research institutes and the Director of the Center for Research Resources (or the designees of such Directors); and

''(B) representatives of the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, the National Science Foundation, and such additional agencies as the Director of NIH determines to be appropriate.''.

(b) CONFORMING AMENDMENT.—Section 4 of the Health Research Extension Act of 1985 (Public Law 99–158; 99 Stat. 880) is repealed.

SEC. 205. INCREASED PARTICIPATION OF WOMEN AND MEMBERS OF UNDERREPRESENTED MINORITIES IN FIELDS OF BIOMEDICAL AND BEHAVIORAL RESEARCH.

Section 402 of the Public Health Service Act, as amended by section 202 of this Act, is amended by adding at the end the following new subsection:

''(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, may conduct and support programs for research, research training, recruitment, and other activities to provide for an increase in the number of women

and members of underrepresented minority groups in the fields of biomedical and behavioral research.''.

SEC. 206. REQUIREMENTS REGARDING SURVEYS OF SEXUAL BEHAVIOR.

Part A of title IV of the Public Health Service Act, as amended by section 204 of this Act, is amended by adding at the end the following new section:

''REQUIREMENTS REGARDING SURVEYS OF SEXUAL BEHAVIOR

''SEC. 404B. With respect to any survey of human sexual behavior proposed to be conducted or supported through the National Institutes of Health, the survey may not be carried out unless—

''(1) the proposal has undergone review in accordance with any applicable requirements of sections 491 and 492; and

''(2) the Secretary, in accordance with section 492A, makes a determination that the information expected to be obtained through the survey will assist—

''(A) in reducing the incidence of sexually transmitted diseases, the incidence of infection with the human immunodeficiency virus, or the incidence of any other infectious disease; or

''(B) in improving reproductive health or other conditions of health.''.

SEC. 207. DISCRETIONARY FUND OF DIRECTOR OF NATIONAL INSTITUTES OF HEALTH.

Section 402 of the Public Health Service Act, as amended by section 205 of this Act, is amended by adding at the end the following new subsection:

''(i)(1) There is established a fund, consisting of amounts appropriated under paragraph (3) and made available for the fund, for use by the Director of NIH to carry out the activities authorized in this Act for the National Institutes of Health. The purposes for which such fund may be expended include—

''(A) providing for research on matters that have not received significant funding relative to other matters, responding to new issues and scientific emergencies, and acting on research opportunities of high priority;

''(B) supporting research that is not exclusively within the authority of any single agency of such Institutes; and

''(C) purchasing or renting equipment and quarters for activities of such Institutes.

''(2) Not later than February 10 of each fiscal year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities undertaken and

expenditures made under this section during the preceding fiscal year. The report may contain such comments of the Secretary regarding this section as the Secretary determines to be appropriate.

''(3) For the purpose of carrying out this subsection, there are authorized to be appropriated $25,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 208. MISCELLANEOUS PROVISIONS.

(a) TERM OF OFFICE FOR MEMBERS OF ADVISORY COUNCILS.—Section 406(c) of the Public Health Service Act (42 U.S.C. 284a(c)) is amended in the second sentence by striking ''until a successor has been appointed'' and inserting the following: ''for 180 days after the date of such expiration''.

(b) LITERACY REQUIREMENTS.—Section 402(e) of the Public Health Service Act (42 U.S.C. 282(e)) is amended—

(1) in paragraph (3), by striking ''and'' at the end;

(2) in paragraph (4), by striking the period and inserting ''; and''; and

(3) by adding at the end thereof the following new paragraph:

''(5) ensure that, after January 1, 1994, at least one-half of all new or revised health education and promotion materials developed or funded by the National Institutes of Health is in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102–73).''.

(c) DAY CARE REGARDING CHILDREN OF EMPLOYEES.—Section 402 of the Public Health Service Act, as amended by section 207 of this Act, is amended by adding at the end the following new subsection:

''(i)(1) The Director of NIH may establish a program to provide day care service for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

''(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

''(3) For purposes regarding the provision of day care service, the Director of NIH may enter into rental or lease purchase agreements.''.

TITLE III—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

SEC. 301. APPOINTMENT AND AUTHORITY OF DIRECTORS OF NATIONAL RESEARCH INSTITUTES.

(a) ESTABLISHMENT OF GENERAL AUTHORITY REGARDING DIRECT FUNDING.—

(1) IN GENERAL.—Section 405(b)(2) of the Public Health Service Act (42 U.S.C. 284(b)(2)) is amended—

(A) in subparagraph (A), by striking ''and'' after the semicolon at the end;

(B) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following new subparagraph:

''(C) shall receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.''.

(2) CONFORMING AMENDMENT.—Section 413(b)(9) of the Public Health Service Act (42 U.S.C. 285a–2(b)(9)) is amended—

(A) by striking ''(A)'' after ''(9)''; and

(B) by striking ''advisory council;'' and all that follows and inserting ''advisory council.''.

(b) APPOINTMENT AND DURATION OF TECHNICAL AND SCIENTIFIC PEER REVIEW GROUPS.—Section 405(c) of the Public Health Service Act (42 U.S.C. 284(c)) is amended—

(1) by amending paragraph (3) to read as follows:

''(3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

''(A) establish technical and scientific peer review groups in addition to those appointed under section 402(b)(6); and

''(B) appoint the members of peer review groups established under subparagraph (A); and''; and

(2) by adding after and below paragraph (4) the following:

''The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (3).''.

SEC. 302. PROGRAM OF RESEARCH ON OSTEOPOROSIS, PAGET'S DISEASE, AND RELATED BONE DISORDERS.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.), as amended by section 121(b) of Public Law 102–321 (106 Stat. 358), is amended by adding at the end the following new section:

''RESEARCH ON OSTEOPOROSIS, PAGET'S DISEASE, AND RELATED BONE DISORDERS

''SEC. 410. (a) ESTABLISHMENT.—The Directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, the National Institute of Diabetes, Digestive and Kidney Diseases, and the National Institute of Dental Research, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

''(b) COORDINATION.—The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the Interagency Task Force on Aging Research.

''(c) INFORMATION CLEARINGHOUSE.—

''(1) IN GENERAL.—In order to assist in carrying out the purpose described in subsection (a), the

Director of NIH shall provide for the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information.

''(2) ESTABLISHMENT THROUGH GRANT OR CONTRACT.—For the purpose of carrying out paragraph (1), the Director of NIH shall enter into a grant, cooperative agreement, or contract with a nonprofit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 303. ESTABLISHMENT OF INTERAGENCY PROGRAM FOR TRAUMA RESEARCH.

(a) IN GENERAL.—Title XII of the Public Health Service Act (42 U.S.C. 300d et seq.) is amended by adding at the end the following part:

''PART E—INTERAGENCY PROGRAM FOR TRAUMA RESEARCH

"SEC. 1251. ESTABLISHMENT OF PROGRAM.

''(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health (hereafter in this section referred to as the 'Director'), shall establish a comprehensive program of conducting basic and clinical research on trauma (hereafter in this section referred to as the 'Program'). The Program shall include research regarding the diagnosis, treatment, rehabilitation, and general management of trauma.

(b) PLAN FOR PROGRAM.—

''(1) IN GENERAL.—The Director, in consultation with the Trauma Research Interagency Coordinating Committee established under subsection (g), shall establish and implement a plan for carrying out the activities of the Program, including the activities described in subsection (d). All such activities shall be carried out in accordance with the plan. The plan shall be periodically reviewed, and revised as appropriate.

''(2) SUBMISSION TO CONGRESS.—Not later than one year after the date of enactment of this section, the Director shall submit the plan required in paragraph (1) to the Committee on Energy and

Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, together with an estimate of the funds needed for each of the fiscal years 1994 through 1996 to implement the plan.

''(c) PARTICIPATING AGENCIES; COORDINATION AND COLLABORATION.—The Director—

''(1) shall provide for the conduct of activities under the Program by the Directors of the agencies of the National Institutes of Health involved in research with respect to trauma;

''(2) shall ensure that the activities of the Program are coordinated among such agencies; and

''(3) shall, as appropriate, provide for collaboration among such agencies in carrying out such activities.

''(d) CERTAIN ACTIVITIES OF PROGRAM.—The Program shall include—

''(1) studies with respect to all phases of trauma care, including prehospital, resuscitation, surgical intervention, critical care, infection control, wound healing, nutritional care and support, and medical rehabilitation care;

''(2) basic and clinical research regarding the response of the body to trauma and the acute treat-

ment and medical rehabilitation of individuals who are the victims of trauma; and

''(3) basic and clinical research regarding trauma care for pediatric and geriatric patients.

''(e) MECHANISMS OF SUPPORT.—In carrying out the Program, the Director, acting through the Directors of the agencies referred to in subsection (c)(1), may make grants to public and nonprofit entities, including designated trauma centers.

''(f) RESOURCES.—The Director shall assure the availability of appropriate resources to carry out the Program, including the plan established under subsection (b) (including the activities described in subsection (d)).

''(g) COORDINATING COMMITTEE.—

''(1) IN GENERAL.—There shall be established a Trauma Research Interagency Coordinating Committee (hereafter in this section referred to as the 'Coordinating Committee').

''(2) DUTIES.—The Coordinating Committee shall make recommendations regarding—

''(A) the activities of the Program to be carried out by each of the agencies represented on the Committee and the amount of funds needed by each of the agencies for such activities; and

''(B) effective collaboration among the agencies in carrying out the activities.

''(3) COMPOSITION.—The Coordinating Committee shall be composed of the Directors of each of the agencies that, under subsection (c), have responsibilities under the Program, and any other individuals who are practitioners in the trauma field as designated by the Director of the National Institutes of Health.

''(h) DEFINITIONS.—For purposes of this section:

''(1) The term 'designated trauma center' has the meaning given such term in section 1231(1).

''(2) The term 'Director' means the Director of the National Institutes of Health.

''(3) The term 'trauma' means any serious injury that could result in loss of life or in significant disability and that would meet pre-hospital triage criteria for transport to a designated trauma center.''.

(b) CONFORMING AMENDMENT.—Section 402 of the Public Health Service Act, as amended by section 208(c) of this Act, is amended by adding at the end the following new subsection:

''(k) The Director of NIH shall carry out the program established in part E of title XII (relating to interagency research on trauma).''.

TITLE IV—NATIONAL CANCER INSTITUTE

SEC. 401. EXPANSION AND INTENSIFICATION OF ACTIVITIES REGARDING BREAST CANCER.

Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following new section:

''BREAST AND GYNECOLOGICAL CANCERS

''SEC. 417. (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on breast cancer, ovarian cancer, and other cancers of the reproductive system of women.

''(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to breast cancer and other cancers of the reproductive system of women.

''(c) PROGRAMS FOR BREAST CANCER.—

''(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, breast cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

''(A) basic research concerning the etiology and causes of breast cancer;

''(B) clinical research and related activities concerning the causes, prevention, detection and treatment of breast cancer;

''(C) control programs with respect to breast cancer in accordance with section 412;

''(D) information and education programs with respect to breast cancer in accordance with section 413; and

''(E) research and demonstration centers with respect to breast cancer in accordance with section 414, including the development and operation of centers for breast cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and

treatment research and related activities on breast cancer.

Not less than six centers shall be operated under subparagraph (E). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

''(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

''(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9). The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

''(B) Not later than May 1, 1993, the Director of the Institute shall submit a copy of

the plan to the President's Cancer Panel, the Secretary and the Director of NIH.

''(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

''(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

''(d) OTHER CANCERS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research on ovarian cancer and other cancers of the reproductive system of women. Activities under such subsection shall provide for the conduct and support of—

''(1) basic research concerning the etiology and causes of ovarian cancer and other cancers of the reproductive system of women;

''(2) clinical research and related activities into the causes, prevention, detection and treatment of ovarian cancer and other cancers of the reproductive system of women;

''(3) control programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 412;

''(4) information and education programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 413; and

''(5) research and demonstration centers with respect to ovarian cancer and cancers of the reproductive system in accordance with section 414.

''(e) REPORT.—The Director of the Institute shall prepare, for inclusion in the biennial report submitted under section 407, a report that describes the activities of the National Cancer Institute under the research programs referred to in subsection (a), that shall include—

''(1) a description of the research plan with respect to breast cancer prepared under subsection (c);

''(2) an assessment of the development, revision, and implementation of such plan;

''(3) a description and evaluation of the progress made, during the period for which such report is prepared, in the research programs on breast cancer and cancers of the reproductive system of women;

''(4) a summary and analysis of expenditures made, during the period for which such report is made, for activities with respect to breast cancer and cancers of the reproductive system of women conducted and supported by the National Institutes of Health; and

''(5) such comments and recommendations as the Director considers appropriate.''.

SEC. 402. EXPANSION AND INTENSIFICATION OF ACTIVITIES REGARDING PROSTATE CANCER.

Subpart 1 of part C of title IV of the Public Health Service Act, as amended by section 401 of this Act, is amended by adding at the end the following new section:

''PROSTATE CANCER

''SEC. 417A. (a) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on prostate cancer.

''(b) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to prostate cancer.

''(c) PROGRAMS.—

''(1) IN GENERAL.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, prostate cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

''(A) basic research concerning the etiology and causes of prostate cancer;

''(B) clinical research and related activities concerning the causes, prevention, detection and treatment of prostate cancer;

''(C) prevention and control and early detection programs with respect to prostate cancer in accordance with section 412, particularly as it relates to intensifying research on the role of prostate specific antigen for the screening and early detection of prostate cancer;

''(D) an Inter-Institute Task Force, under the direction of the Director of the Institute, to provide coordination between relevant National Institutes of Health components of research efforts on prostate cancer;

''(E) control programs with respect to prostate cancer in accordance with section 412;

''(F) information and education programs with respect to prostate cancer in accordance with section 413; and

''(G) research and demonstration centers with respect to prostate cancer in accordance with section 414, including the development and operation of centers for prostate cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and treatment research and related activities on prostate cancer.

Not less than six centers shall be operated under subparagraph (G). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

''(2) IMPLEMENTATION OF PLAN FOR PROGRAMS.—

''(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance

with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 413(9). The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

''(B) Not later than May 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary and the Director of NIH.

''(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

''(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.''.

SEC. 403. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Subpart 1 of part C of title IV of the Public Health Service Act, as amended by section 402 of this Act, is amended by adding at the end the following new section:

''AUTHORIZATION OF APPROPRIATIONS

''SEC. 417B. (a) ACTIVITIES GENERALLY.—For the purpose of carrying out this subpart, there are authorized to be appropriated $2,200,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

''(b) BREAST CANCER AND GYNECOLOGICAL CANCERS.—

''(1) BREAST CANCER.—

''(A) For the purpose of carrying out subparagraph (A) of section 417(c)(1), there are authorized to be appropriated $225,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

''(B) For the purpose of carrying out subparagraphs (B) through (E) of section 417(c)(1), there are authorized to be appro-

priated $100,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

''(2) OTHER CANCERS.—For the purpose of carrying out subsection (d) of section 417, there are authorized to be appropriated $75,000,000 for fiscal year 1994, and such sums as are necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

''(c) PROSTATE CANCER.—For the purpose of carrying out section 417A, there are authorized to be appropriated $72,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

''(d) ALLOCATION REGARDING CANCER CONTROL.—Of the amounts appropriated for the National Cancer Institute for a fiscal year, the Director of the Institute is authorized to make available not less than 10 percent for

carrying out the cancer control activities authorized in section 412 and for which budget estimates are made under section 413(b)(9) for the fiscal year.''.

(b) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 408 of the Public Health Service Act (42 U.S.C. 284c) is amended—

(A) by striking subsection (a);

(B) by redesignating subsection (b) as subsection (a);

(C) by redesignating paragraph (5) of subsection (a) (as so redesignated) as subsection (b); and

(D) by amending the heading for the section to read as follows:

''CERTAIN USES OF FUNDS''.

(2) CROSS-REFERENCE.—Section 464F of the Public Health Service Act (42 U.S.C. 285m–6) is amended by striking ''section 408(b)(1)'' and inserting ''section 408(a)(1)''.

TITLE V—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

SEC. 501. EDUCATION AND TRAINING.

Section 421(b) of the Public Health Service Act (42 U.S.C. 285b–3(b)) is amended—

(1) in paragraph (3), by striking ''and'' after the semicolon at the end;

(2) in paragraph (4), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (4) the following new paragraph:

''(5) shall, in consultation with the advisory council for the Institute, conduct appropriate intramural training and education programs, including continuing education and laboratory and clinical research training programs.''.

SEC. 502. CENTERS FOR THE STUDY OF PEDIATRIC CARDIOVASCULAR DISEASES.

Section 422(a)(1) of the Public Health Service Act (42 U.S.C. 285b–4(a)(1)) is amended—

(1) in subparagraph (B), by striking ''and'' at the end;

(2) in subparagraph (C), by striking the period and inserting ''; and''; and

(3) by adding at the end thereof the following new subparagraph:

''(D) three centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment (including genetic studies, intrauterine environment studies, postnatal studies, heart arrhythmias, and

acquired heart disease and preventive cardiology) for cardiovascular diseases in children.''.

SEC. 503. NATIONAL CENTER ON SLEEP DISORDERS RESEARCH.

Subpart 2 of part C of title IV of the Public Health Service Act (42 U.S.C. 285b et seq.) is amended by adding at the end the following new section:

''NATIONAL CENTER ON SLEEP DISORDERS RESEARCH

''SEC. 424. (a) Not later than 1 year after the date of the enactment of the National Institutes of Health Revitalization Act of 1993, the Director of the Institute shall establish the National Center on Sleep Disorders Research (in this section referred to as the 'Center'). The Center shall be headed by a director, who shall be appointed by the Director of the Institute.

''(b) The general purpose of the Center is—

''(1) the conduct and support of research, training, health information dissemination, and other activities with respect to sleep disorders, including biological and circadian rhythm research, basic understanding of sleep, chronobiological and other sleep related research; and

''(2) to coordinate the activities of the Center with similar activities of other Federal agencies, including the other agencies of the National Institutes

of Health, and similar activities of other public entities and nonprofit entities.

''(c)(1) The Director of the National Institutes of Health shall establish a committee to be known as the Sleep Disorders Coordinating Committee (hereafter in this section referred to as the 'Coordinating Committee').

''(2) The Coordinating Committee shall be composed of the directors of the National Institutes of Health, the National Institute on Aging, the National Institute of Child Health and Human Development, the National Heart, Lung and Blood Institute, the National Institute of Neurological Disorders and Stroke, the National Institute of Mental Health, and of such other national research institutes as the Director of the National Institutes of Health determines to be appropriate, and shall include representation from other Federal departments and agencies whose programs involve sleep disorders.

''(3) The Director of the National Health, Lung, and Blood Institute shall serve as the chairperson of the Coordinating Committee.

''(4) The Coordinating Committee shall make recommendations to the Director of the National Institutes of Health and the Director of the Center with respect to the content of the plan required in subsection (e), with respect to the activities of the Center that are carried out

in conjunction with other agencies of the National Institutes of Health, and with respect to the activities of the Center that are carried out in conjunction with other agencies of the Federal Government.

''(d)(1) The Director of the National Institutes of Health shall establish a board to be known as the Sleep Disorders Research Advisory Board (hereafter in this section referred to as the 'Advisory Board').

''(2) The Advisory Board shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health, through the Director of the Institute, and the Director of the Center concerning matters relating to the scientific activities carried out by and through the Center and the policies respecting such activities, including recommendations with respect to the plan required in subsection (c).

''(3)(A) The Director of the National Institutes of Health shall appoint to the Advisory Board 12 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, eight shall be representatives of health and scientific disciplines with respect to sleep disorders and four shall be individuals representing the interests of individuals with or undergoing treatment for sleep disorders.

''(B) The following officials shall serve as ex officio members of the Advisory Board:

''(i) The Director of the National Institutes of Health.

''(ii) The Director of the Center.

''(iii) The Director of the National Heart, Lung and Blood Institute.

''(iv) The Director of the National Institute of Mental Health.

''(v) The Director of the National Institute on Aging.

''(vi) The Director of the National Institute of Child Health and Human Development.

''(vii) The Director of the National Institute of Neurological Disorders and Stroke.

''(viii) The Assistant Secretary for Health.

''(ix) The Assistant Secretary of Defense (Health Affairs).

''(x) The Chief Medical Director of the Veterans' Administration.

''(4) The members of the Advisory Board shall, from among the members of the Advisory Board, designate an individual to serve as the chairperson of the Advisory Board.

''(5) Except as inconsistent with, or inapplicable to, this section, the provisions of section 406 shall apply to the advisory board established under this section in the same manner as such provisions apply to any advisory council established under such section.

''(e)(1) After consultation with the Director of the Center, the advisory board established under subsection (d), and the coordinating committee established under subsection (c), the Director of the National Institutes of Health shall develop a comprehensive plan for the conduct and support of sleep disorders research.

''(2) The plan developed under paragraph (1) shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.

''(3) The Director of the National Institutes of Health (after consultation with the Director of the Center, the advisory board established under subsection (d), and the coordinating committee established under subsection (c)) shall revise the plan developed under paragraph (1) as appropriate.

''(f) The Director of the Center, in cooperation with the Centers for Disease Control, is authorized to coordinate activities with the Department of Transportation, the

Department of Defense, the Department of Education, the Department of Labor, and the Department of Commerce to collect data, conduct studies, and disseminate public information concerning the impact of sleep disorders and sleep deprivation.''.

SEC. 504. AUTHORIZATION OF APPROPRIATIONS.

Subpart 2 of part C of title IV of the Public Health Service Act, as amended by section 503 of this Act, is amended by adding at the end the following section:

''AUTHORIZATION OF APPROPRIATIONS

''SEC. 425. (a) For the purpose of carrying out this subpart, there are authorized to be appropriated $1,500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

''(b) Of the amounts appropriated under paragraph (1) for a fiscal year, the Director of the Institute is authorized to make available not less than 10 percent for carrying out community-based prevention and control activities that include clinical investigations, clinical trials, epidemiologic studies, and prevention demonstration and education projects.''.

TITLE VI—NATIONAL INSTITUTE ON DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SEC. 601. PROVISIONS REGARDING NUTRITIONAL DISORDERS.

Subpart 3 of part C of title IV of the Public Health Service Act (42 U.S.C. 285c et seq.) is amended by adding at the end the following new section:

''NUTRITIONAL DISORDERS PROGRAM

''SEC. 434. (a) The Director of the Institute shall establish a program of conducting and supporting research, training, health information dissemination, and other activities with respect to nutritional disorders, including obesity.

''(b) In carrying out the program established under subsection (a), the Director of the Institute shall conduct and support each of the activities described in such subsection. The Director of NIH shall ensure that, as appropriate, the other national research institutes and agencies of the National Institutes of Health have responsibilities regarding such activities.

''(c) In carrying out the program established under subsection (a), the Director of the Institute shall carry out activities to facilitate and enhance knowledge and understanding of nutritional disorders, including obesity, on the

part of health professionals, patients, and the public through the effective dissemination of information.''.

(b) DEVELOPMENT AND EXPANSION OF RESEARCH AND TRAINING CENTERS.—Section 431 of the Public Health Service Act (42 U.S.C. 285c–5) is amended—

(1) by redesignating subsection (d) as subsection (e); and

(2) by inserting after subsection (c) the following new subsection:

''(d)(1) The Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the development or substantial expansion of centers for research and training regarding nutritional disorders, including obesity.

''(2) The Director of the Institute shall carry out paragraph (1) in collaboration with the Director of the National Cancer Institute and with the Directors of such other agencies of the National Institutes of Health as the Director of NIH determines to be appropriate.

''(3) Each center developed or expanded under paragraph (1) shall—

''(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director;

''(B) conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of nutritional disorders, including obesity and the impact of nutrition and diet on child development;

''(C) conduct training programs for physicians and allied health professionals in current methods of diagnosis and treatment of such diseases and complications, and in research in such disorders; and

''(D) conduct information programs for physicians and allied health professionals who provide primary care for patients with such disorders or complications.''.

TITLE VII—NATIONAL INSTITUTE ON ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

SEC. 701. JUVENILE ARTHRITIS.

(a) PURPOSE.—Section 435 of the Public Health Service Act (42 U.S.C. 285d) is amended by striking ''and other programs'' and all that follows and inserting the following: ''and other programs with respect to arthritis and musculoskeletal and skin diseases (including sports-related disorders), with particular attention to the effect of these diseases on children.''.

(b) PROGRAMS.—Section 436 (42 U.S.C. 285d–1) is amended—

(1) in subsection (a), by inserting after the second sentence, the following: ''The plan shall place particular emphasis upon expanding research into better understanding the causes and the development of effective treatments for arthritis affecting children.''; and

(2) in subsection (b)—

(A) by striking ''and'' at the end of paragraph (3);

(B) by striking the period at the end of paragraph (4) and inserting ''; and''; and

(C) by adding at the end thereof the following new paragraph:

''(5) research into the causes of arthritis affecting children and the development, trial, and evaluation of techniques, drugs and devices used in the diagnosis, treatment (including medical rehabilitation), and prevention of arthritis in children.''.

(c) CENTERS.—Section 441 of the Public Health Service Act (42 U.S.C. 286d–6) is amended by adding at the end thereof the following new subsection:

''(f) Not later than October 1, 1994, the Director shall establish a multipurpose arthritis and musculo-

skeletal disease center for the purpose of expanding the level of research into the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.''.

(d) ADVISORY BOARD.—

(1) TITLE.—Section 442(a) of the Public Health Service Act (42 U.S.C. 285d–7(a)) is amended by inserting after ''Arthritis'' the the first place such term appears the following: ''and Musculoskeletal and Skin Diseases''.

(2) COMPOSITION.—Section 442(b) of the Public Health Service Act (42 U.S.C. 285d–7(b)) is amended—Section 442(b) of the Public Health Service Act (42 U.S.C. 285d–7(b)) is amended—

(A) in the matter preceding paragraph (1), by striking ''eighteen'' and inserting ''twenty''; and

(B) in paragraph (1)(B)—

(i) by striking ''six'' and inserting ''eight''; and

(ii) by striking ''including'' and all that follows and inserting the following: ''including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease,

and two members who are parents of children with arthritis.''.

(3) ANNUAL REPORT.—Section 442(j) of the Public Health Service Act (42 U.S.C. 285d–7(j)) is amended—

(1) by striking ''and'' at the end of paragraph (3);

(2) by striking the period at the end of paragraph (4) and inserting ''; and''; and

(3) by adding at the end the following paragraph:

''(5) contains recommendations for expanding the Institute's funding of research directly applicable to the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.''.

TITLE VIII—NATIONAL INSTITUTE ON AGING

SEC. 801. ALZHEIMER'S DISEASE REGISTRY.

(a) IN GENERAL.—Section 12 of Public Law 99–158 (99 Stat. 885) is—

(1) transferred to subpart 5 of part C of title IV of the Public Health Service Act (42 U.S.C. 285e et seq.);

(2) redesignated as section 445G; and

(3) inserted after section 445F of such Act.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—Section 445G of the Public Health Service Act, as transferred and inserted by subsection (a) of this section, is amended—

(1) by striking the section heading and all that follows through ''may make a grant'' in subsection (a) and inserting the following:

''ALZHEIMER'S DISEASE REGISTRY

''SEC. 445G. (a) IN GENERAL.—The Director of the Institute may make a grant''; and

(2) by striking subsection (c).

SEC. 802. AGING PROCESSES REGARDING WOMEN.

Subpart 5 of part C of title IV of the Public Health Service Act, as amended by section 801 of this Act, is amended by adding at the end the following new section:

''AGING PROCESSES REGARDING WOMEN

''SEC. 445H. The Director of the Institute, in addition to other special functions specified in section 444 and in cooperation with the Directors of the other national research institutes and agencies of the National Institutes of Health, shall conduct research into the aging processes of women, with particular emphasis given to the effects of menopause and the physiological and behavioral changes occurring during the transition from pre- to post-menopause, and into the diagnosis, disorders, and com-

plications related to aging and loss of ovarian hormones in women.''.

SEC. 803. AUTHORIZATION OF APPROPRIATIONS.

Subpart 5 of part C of title IV of the Public Health Service Act, as amended by section 802 of this Act, is amended by adding at the end the following new section:

''AUTHORIZATION OF APPROPRIATIONS

''SEC. 445I. For the purpose of carrying out this subpart, there are authorized to be appropriated $500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 804. CONFORMING AMENDMENT.

Section 445C of the Public Health Service Act (42 U.S.C. 285e–5(b)) is amended—

(1) in subsection (b)(1), in the first sentence, by inserting after ''Council'' the following: ''on Alzheimer's Disease (hereafter in this section referred to as the 'Council')''; and

(2) by adding at the end the following new subsection:

''(d) For purposes of this section, the term 'Council on Alzheimer's Disease' means the council established in section 911(a) of Public Law 99–660.''.

TITLE IX—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SEC. 901. TROPICAL DISEASES.

Section 446 of the Public Health Service Act (42 U.S.C. 285f) is amended by inserting before the period the following: ‘‘, including tropical diseases’’.

SEC. 902. CHRONIC FATIGUE SYNDROME.

(a) RESEARCH CENTERS.—Subpart 6 of part C of title IV of the Public Health Service Act (42 U.S.C. 285f) is amended by adding at the end the following new section:

‘‘RESEARCH CENTERS REGARDING CHRONIC FATIGUE SYNDROME

‘‘SEC. 447. (a) The Director of the Institute, after consultation with the advisory council for the Institute, may make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct basic and clinical research on chronic fatigue syndrome.

‘‘(b) Each center assisted under this section shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.’’.

(b) EXTRAMURAL STUDY SECTION.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall establish an extramural study section for chronic fatigue syndrome research.

(c) REPRESENTATIVES.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall ensure that appropriate individuals with expertise in chronic fatigue syndrome or neuromuscular diseases and representative of a variety of disciplines and fields within the research community are appointed to appropriate National Institutes of Health advisory committees and boards.

TITLE X—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Subtitle A—Research Centers With Respect to Contraception and Research Centers With Respect to Infertility

SEC. 1001. GRANTS AND CONTRACTS FOR RESEARCH CENTERS.

Subpart 7 of part C of title IV of the Public Health Service Act, as amended by section 3 of Public Law 101–

613, is amended by adding at the end the following new section:

''RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION AND INFERTILITY

''SEC. 452A. (a) The Director of the Institute, after consultation with the advisory council for the Institute, shall make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct activities for the purpose of improving methods of contraception and centers to conduct activities for the purpose of improving methods of diagnosis and treatment of infertility.

''(b) In carrying out subsection (a), the Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the establishment of three centers with respect to contraception and for two centers with respect to infertility.

''(c)(1) Each center assisted under this section shall, in carrying out the purpose of the center involved—

''(A) conduct clinical and other applied research, including—

''(i) for centers with respect to contraception, clinical trials of new or improved drugs and devices for use by males and females (including barrier methods); and

''(ii) for centers with respect to infertility, clinical trials of new or improved drugs and devices for the diagnosis and treatment of infertility in males and females;

''(B) develop protocols for training physicians, scientists, nurses, and other health and allied health professionals;

''(C) conduct training programs for such individuals;

''(D) develop model continuing education programs for such professionals; and

''(E) disseminate information to such professionals and the public.

''(2) A center may use funds provided under subsection (a) to provide stipends for health and allied health professionals enrolled in programs described in subparagraph (C) of paragraph (1), and to provide fees to individuals serving as subjects in clinical trials conducted under such paragraph.

''(d) The Director of the Institute shall, as appropriate, provide for the coordination of information among the centers assisted under this section.

''(e) Each center assisted under subsection (a) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such re-

quirements as may be prescribed by the Director of the Institute.

''(f) Support of a center under subsection (a) may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

''(g) For the purpose of carrying out this section, there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 1002. LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY.

Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act, is amended by inserting after section 487A the following section:

''LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO CONTRACEPTION AND INFERTILITY

''SEC. 487B. (a) The Secretary, in consultation with the Director of the National Institute of Child Health and Human Development, shall establish a program of entering into agreements with qualified health professionals (in-

cluding graduate students) under which such health professionals agree to conduct research with respect to contraception, or with respect to infertility, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of such health professionals.

''(b) The provisions of sections 338B, 338C, and 338E shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

''(c) Amounts appropriated for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.''.

Subtitle B—Program Regarding Obstetrics and Gynecology

SEC. 1011. ESTABLISHMENT OF PROGRAM.

Subpart 7 of part C of title IV of the Public Health Service Act, as amended by section 1001 of this Act, is amended by adding at the end the following new section:

''PROGRAM REGARDING OBSTETRICS AND GYNECOLOGY

''SEC. 452B. The Director of the Institute shall establish and maintain within the Institute an intramural

laboratory and clinical research program in obstetrics and gynecology.''.

Subtitle C—Child Health Research Centers

SEC. 1021. ESTABLISHMENT OF CENTERS.

Subpart 7 of part C of title IV of the Public Health Service Act, as amended by section 1011 of this Act, is amended by adding at the end the following new section:

''CHILD HEALTH RESEARCH CENTERS

''SEC. 452C. The Director of the Institute shall develop and support centers for conducting research with respect to child health. Such centers shall give priority to the expeditious transfer of advances from basic science to clinical applications and improving the care of infants and children.''.

Subtitle D—Study Regarding Adolescent Health

SEC. 1031. PROSPECTIVE LONGITUDINAL STUDY.

Subpart 7 of part C of title IV of the Public Health Service Act, as amended by section 1021 of this Act, is amended by adding at the end the following new section:

''PROSPECTIVE LONGITUDINAL STUDY ON ADOLESCENT HEALTH

''SEC. 452D. (a) IN GENERAL.—Not later than November 1, 1993, the Director of the Institute shall initiate a 3-year study for the purpose of providing information

on the general health and well-being of adolescents in the United States, including, with respect to such adolescents, information on—

''(1) the behaviors that promote health and the behaviors that are detrimental to health; and

''(2) the influence on health of factors particular to the communities in which the adolescents reside.

''(b) DESIGN OF STUDY.—

''(1) IN GENERAL.—The study required in subsection (a) shall be a longitudinal study in which a substantial number of adolescents participate as subjects. With respect to the purpose described in such subsection, the study shall monitor the subjects throughout the period of the study to determine the health status of the subjects and any change in such status over time.

''(2) POPULATION-SPECIFIC ANALYSES.—The study required in subsection (a) shall be conducted with respect to the population of adolescents who are female, the population of adolescents who are male, various socioeconomic populations of adolescents, and various racial and ethnic populations of adolescents. The study shall be designed and conducted in a manner sufficient to provide for a valid analysis of

whether there are significant differences among such populations in health status and whether and to what extent any such differences are due to factors particular to the populations involved.

''(c) COORDINATION WITH WOMEN'S HEALTH INITIATIVE.—With respect to the national study of women being conducted by the Secretary and known as the Women's Health Initiative, the Secretary shall ensure that such study is coordinated with the component of the study required in subsection (a) that concerns adolescent females, including coordination in the design of the 2 studies.''.

TITLE XI—NATIONAL EYE INSTITUTE

SEC. 1101. CLINICAL AND HEALTH SERVICES RESEARCH ON EYE CARE AND DIABETES.

(a) IN GENERAL.—Subpart 9 of part C of title IV of the Public Health Service Act (42 U.S.C. 285i) is amended by adding at the end the following new section:

''CLINICAL RESEARCH ON EYE CARE AND DIABETES

''SEC. 456. (a) PROGRAM OF GRANTS.—The Director of the Institute, in consultation with the advisory council for the Institute, may award research grants to one or more Diabetes Eye Research Institutions for the support of programs in clinical or health services aimed at—

''(1) providing comprehensive eye care services for people with diabetes, including a full complement of preventive, diagnostic and treatment procedures;

''(2) developing new and improved techniques of patient care through basic and clinical research;

''(3) assisting in translation of the latest research advances into clinical practice; and

''(4) expanding the knowledge of the eye and diabetes through further research.

''(b) USE OF FUNDS.—Amounts received under a grant awarded under this section shall be used for the following:

''(1) Establishing the biochemical, cellular, and genetic mechanisms associated with diabetic eye disease and the earlier detection of pending eye abnormalities. The focus of work under this paragraph shall require that ophthalmologists have training in the most up-to-date molecular and cell biological methods.

''(2) Establishing new frontiers in technology, such as video-based diagnostic and research resources, to—

''(A) provide improved patient care;

''(B) provide for the evaluation of retinal physiology and its affect on diabetes; and

''(C) provide for the assessment of risks for the development and progression of diabetic eye disease and a more immediate evaluation of various therapies aimed at preventing diabetic eye disease.

Such technologies shall be designed to permit evaluations to be performed both in humans and in animal models.

''(3) The translation of the results of vision research into the improved care of patients with diabetic eye disease. Such translation shall require the application of institutional resources that encompass patient care, clinical research and basic laboratory research.

''(4) The conduct of research concerning the outcomes of eye care treatments and eye health education programs as they relate to patients with diabetic eye disease, including the evaluation of regional approaches to such research.

''(c) AUTHORIZED EXPENDITURES.—The purposes for which a grant under subsection (a) may be expended include equipment for the research described in such subsection and the construction and modernization of facilities for such research.''.

(b) CONFORMING AMENDMENT.—Section 455 of the Public Health Service Act (42 U.S.C. 285i) is amended in the second sentence by striking ''The Director'' and inserting ''Subject to section 456, the Director''.

TITLE XII—NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

SEC. 1201. RESEARCH ON MULTIPLE SCLEROSIS.

Subpart 10 of part C of title IV of the Public Health Service Act (42 U.S.C. 285j et seq.) is amended by adding at the end the following new section:

''RESEARCH ON MULTIPLE SCLEROSIS

''SEC. 460. The Director of the Institute shall conduct and support research on multiple sclerosis, especially research on effects of genetics and hormonal changes on the progress of the disease.''.

TITLE XIII—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

SEC. 1301. APPLIED TOXICOLOGICAL RESEARCH AND TESTING PROGRAM.

(a) IN GENERAL.—Subpart 12 of part C of title IV of the Public Health Service Act (42 U.S.C. 285l) is amended by adding at the end the following new section:

''APPLIED TOXICOLOGICAL RESEARCH AND TESTING PROGRAM

''SEC. 463A. (a) There is established within the Institute a program for conducting applied research and testing regarding toxicology, which program shall be known as the Applied Toxicological Research and Testing Program.

''(b) In carrying out the program established under subsection (a), the Director of the Institute shall, with respect to toxicology, carry out activities—

''(1) to expand knowledge of the health effects of environmental agents;

''(2) to broaden the spectrum of toxicology information that is obtained on selected chemicals;

''(3) to develop and validate assays and protocols, including alternative methods that can reduce or eliminate the use of animals in acute or chronic safety testing;

''(4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;

''(5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and

''(6) to integrate related activities of the Department of Health and Human Services.''.

(b) TECHNICAL AMENDMENT.—Section 463 of the Public Health Service Act (42 U.S.C. 285l) is amended by inserting after ''Sciences'' the following: ''(hereafter in this subpart referred to as the 'Institute')''.

TITLE XIV—NATIONAL LIBRARY OF MEDICINE

Subtitle A—General Provisions

SEC. 1401. ADDITIONAL AUTHORITIES.

(a) IN GENERAL.—Section 465(b) of the Public Health Service Act (42 U.S.C. 286(b)) is amended—

(1) by striking ''and'' after the semicolon at the end of paragraph (5);

(2) by redesignating paragraph (6) as paragraph (8); and

(3) by inserting after paragraph (5) the following new paragraphs:

''(6) publicize the availability from the Library of the products and services described in any of paragraphs (1) through (5);

''(7) promote the use of computers and telecommunications by health professionals (including health professionals in rural areas) for the purpose of improving access to biomedical information for health care delivery and medical research; and''.

(b) LIMITATION REGARDING GRANTS.—Section 474(b)(2) of the Public Health Service Act (42 U.S.C. 286b–S(b)(2)) is amended by striking ''$750,000'' and inserting ''$1,000,000''.

(c) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) REPEAL OF CERTAIN AUTHORITY.—Section 215 of the Department of Health and Human Services Appropriations Act, 1988, as contained in section 101(h) of Public Law 100–202 (101 Stat. 1329–275), is repealed.

(2) APPLICABILITY OF CERTAIN NEW AUTHORITY.—With respect to the authority established for the National Library of Medicine in section 465(b)(6) of the Public Health Service Act, as added by subsection (a) of this section, such authority shall be effective as if the authority had been established on December 22, 1987.

SEC. 1402. AUTHORIZATION OF APPROPRIATIONS.

(a) ESTABLISHMENT OF SINGLE AUTHORIZATION.—Subpart 1 of part D of title IV of the Public Health Serv-

ice Act (42 U.S.C. 286 et seq.) is amended by adding at the end the following section:

''AUTHORIZATION OF APPROPRIATIONS

''SEC. 468. (a) For the purpose of carrying out this part, there are authorized to be appropriated $150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

''(b) Amounts appropriated under subsection (a) and made available for grants or contracts under any of sections 472 through 476 shall remain available until the end of the fiscal year following the fiscal year for which the amounts were appropriated.''.

(b) CONFORMING AMENDMENTS.—Part D of title IV of the Public Health Service Act (42 U.S.C. 286 et seq.) is amended by striking section 469 and section 478(c).

Subtitle B—Financial Assistance

SEC. 1411. ESTABLISHMENT OF PROGRAM OF GRANTS FOR DEVELOPMENT OF EDUCATION TECHNOLOGIES.

Section 473 of the Public Health Service Act (42 U.S.C. 286b–4) is amended by adding at the end the following new subsection:

''(c)(1) The Secretary shall make grants to public or nonprofit private institutions for the purpose of carrying out projects of research on, and development and demonstration of, new education technologies.

''(2) The purposes for which a grant under paragraph (1) may be made include projects concerning—

''(A) computer-assisted teaching and testing of clinical competence at health professions and research institutions;

''(B) the effective transfer of new information from research laboratories to appropriate clinical applications;

''(C) the expansion of the laboratory and clinical uses of computer-stored research databases; and

''(D) the testing of new technologies for training health care professionals.

''(3) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees to make the projects available with respect to—

''(A) assisting in the training of health professions students; and

''(B) enhancing and improving the capabilities of health professionals regarding research and teaching.''.

Subtitle C—National Information Center on Health Services Research and Health Care Technology

SEC. 1421. ESTABLISHMENT OF CENTER.

Part D of title IV of the Public Health Service Act (42 U.S.C. 286 et seq.) is amended by adding at the end the following new subpart:

''Subpart 4—National Information Center on Health Services Research and Health Care Technology

''NATIONAL INFORMATION CENTER

''SEC. 478A. (a) There is established within the Library an entity to be known as the National Information Center on Health Services Research and Health Care Technology (in this section referred to as the 'Center').

''(b) The purpose of the Center is the collection, storage, analysis, retrieval, and dissemination of information on health services research, clinical practice guidelines, and on health care technology, including the assessment of such technology. Such purpose includes developing and maintaining data bases and developing and implementing methods of carrying out such purpose.

''(c) The Director of the Center shall ensure that information under subsection (b) concerning clinical practice guidelines is collected and maintained electronically and

in a convenient format. Such Director shall develop and publish criteria for the inclusion of practice guidelines and technology assessments in the information center database.

''(d) The Secretary, acting through the Center, shall coordinate the activities carried out under this section through the Center with related activities of the Administrator for Health Care Policy and Research.''.

SEC. 1422. CONFORMING PROVISIONS.

(a) IN GENERAL.—Section 903 of the Public Health Service Act, as amended by section 3 of Public Law 102–410 (106 Stat. 2094), is amended to read as follows:

''(e) REQUIRED INTERAGENCY AGREEMENT.—The Administrator and the Director of the National Library of Medicine shall enter into an agreement providing for the implementation of section 478A.''.

(b) RULE OF CONSTRUCTION.—The amendments made by section 3 of Public Law 102–410 (106 Stat. 2094), by section 1421 of this Act, and by subsection (a) of this section may not be construed as terminating the information center on health care technologies and health care technology assessment established under section 904 of the Public Health Service Act, as in effect on the day before the date of the enactment of Public Law 102–410. Such center shall be considered to be the center estab-

lished in section 478A of the Public Health Service Act, as added by section 1421 of this Act, and shall be subject to the provisions of such section 478A.

TITLE XV—OTHER AGENCIES OF NATIONAL INSTITUTES OF HEALTH

Subtitle A—Division of Research Resources

SEC. 1501. REDESIGNATION OF DIVISION AS NATIONAL CENTER FOR RESEARCH RESOURCES.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 401(b)(2)(B), by amending such subparagraph to read as follows:

''(B) The National Center for Research Resources.''; and

(2) in part E—

(A) in the heading for subpart 1, by striking ''Division of'' and inserting ''National Center for'';

(B) in section 479, by striking ''the Division of Research Resources'' and inserting the following: ''the National Center for Research Resources (hereafter in this subpart referred to as the 'Center')'';

(C) in sections 480 and 481, by striking ''the Division of Research Resources'' each place such term appears and inserting ''the Center''; and

(D) in sections 480 and 481, as amended by subparagraph (C), by striking ''the Division'' each place such term appears and inserting ''the Center''.

SEC. 1502. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

Subpart 1 of part E of title IV of the Public Health Service Act (42 U.S.C. 287 et seq.) is amended by adding at the end the following new section:

''BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES

''SEC. 481A. (a) MODERNIZATION AND CONSTRUCTION OF FACILITIES.—

''(1) IN GENERAL.—The Director of NIH, acting through the Director of the Center, may make grants to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, subject to the provisions of this section.

''(2) CONSTRUCTION AND COST OF CONSTRUCTION.—For purposes of this section, the terms 'construction' and 'cost of construction' include the construction of new buildings and the expansion, ren-

ovation, remodeling, and alteration of existing buildings, including architects' fees, but do not include the cost of acquisition of land or off-site improvements.

''(b) SCIENTIFIC AND TECHNICAL REVIEW BOARDS FOR MERIT-BASED REVIEW OF PROPOSALS.—

''(1) IN GENERAL; APPROVAL AS PRECONDITION TO GRANTS.—

''(A) There is established within the Center a Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities (hereafter referred to in this section as the 'Board').

''(B) The Director of the Center may approve an application for a grant under subsection (a) only if—

''(i) the Board has under paragraph (2) recommended the application for approval; or

''(ii) the Director makes a written determination (setting forth in detail the Director's reasons for rejecting the recommendations of the Board) to approve a grant despite the adverse recommendation of the Board.

''(2) DUTIES.—

''(A) The Board shall provide advice to the Director of the Center and the advisory council established under section 480 (hereafter in this section referred to as the 'Advisory Council') on carrying out this section.

''(B) In carrying out subparagraph (A), the Board shall make a determination of the merit of each application submitted for a grant under subsection (a), after consideration of the requirements established in subsection (c), and shall report the results of the determination to the Director of the Center and the Advisory Council. Such determinations shall be conducted in a manner consistent with procedures established under section 492.

''(C) In carrying out subparagraph (A), the Board shall, in the case of applications recommended for approval, make recommendations to the Director and the Advisory Council on the amount that should be provided in the grant.

''(D) In carrying out subparagraph (A), the Board shall prepare an annual report for the Director of the Center and the Advisory Council describing the activities of the Board in

the fiscal year for which the report is made. Each such report shall be available to the public, and shall—

''(i) summarize and analyze expenditures made under this section;

''(ii) provide a summary of the types, numbers, and amounts of applications that were recommended for grants under subsection (a) but that were not approved by the Director of the Center; and

''(iii) contain the recommendations of the Board for any changes in the administration of this section.

''(3) MEMBERSHIP.—

''(A) Subject to subparagraph (B), the Board shall be composed of not more than 9 members appointed by the Secretary, acting through the Director of the National Institutes of Health, and ex officio members as the Director of the Center may determine.

''(B) Not more than 2 individuals who are officers or employees of the Federal Government may serve as members of the Board.

''(4) CERTAIN REQUIREMENTS REGARDING MEMBERSHIP.—In selecting individuals for member-

ship on the Board, the Secretary shall ensure that the members are individuals who, by the virtue of their training or experience, are eminently qualified to perform peer review functions. In selecting such individuals for such membership, the Secretary shall ensure that the members of the Board collectively—

''(A) are experienced in the planning, construction, financing, and administration of entities that conduct biomedical or behavioral research sciences;

''(B) are knowledgeable in making determinations of the need of entities for biomedical or behavioral research facilities, including such facilities for the dentistry, nursing, pharmacy, and allied health professions;

''(C) are knowledgeable in evaluating the relative priorities for applications for grants under subsection (a) in view of the overall research needs of the United States; and

''(D) are experienced with emerging centers of excellence, as described in subsection (c)(3).

''(5) CERTAIN AUTHORITIES.—

''(A) In carrying out paragraph (2), the Board may establish subcommittees, convene

workshops and conferences, and collect data as the Board considers appropriate.

''(B) In carrying out paragraph (2), the Board may establish subcommittees within the Board. Such subcommittees may hold meetings as determined necessary to enable the subcommittee to carry out its duties.

''(6) TERMS.—

''(A) Except as provided in subparagraph (B), each appointed member of the Board shall hold office for a term of 4 years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of the term of the predecessor.

''(B) Of the initial members appointed to the Board (as specified by the Secretary when making the appointments)—

''(i) 3 shall hold office for a term of 3 years;

''(ii) 3 shall hold office for a term of 2 years; and

''(iii) 3 shall hold office for a term of 1 year.

''(C) No member is eligible for reappointment to the Board until 1 year has elapsed after the end of the most recent term of the member.

''(7) COMPENSATION.—Members of board who are not officers or employees of the United States shall receive compensation for each day engaged in carrying out the duties of the board, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.

''(c) REQUIREMENTS FOR GRANTS.—

''(1) IN GENERAL.—The Director of the Center may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

''(A) The applicant is determined by such Director to be competent to engage in the type of research for which the proposed facility is to be constructed.

''(B) The applicant provides assurances satisfactory to the Director that—

''(i) for not less than 20 years after completion of the construction, the facility

will be used for the purposes of research for which it is to be constructed;

''(ii) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility;

''(iii) sufficient funds will be available, when construction is completed, for the effective use of the facility for the research for which it is being constructed; and

''(iv) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

''(C) The applicant meets reasonable qualifications established by the Director with respect to—

''(i) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding the capacity for biomedical or behavioral research and in improving the quality of such research;

''(ii) the quality of the research or training, or both, to be carried out in the facilities involved;

''(iii) the need of the applicant for such facilities in order to maintain or expand the applicant's research and training mission;

''(iv) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and

''(v) the age and condition of existing research facilities and equipment.

''(D) The applicant has demonstrated a commitment to enhancing and expanding the research productivity of the applicant.

''(2) CONSIDERATION OF CERTAIN FACTORS.—In making grants under subsection (a), the Director of the Center may, in addition to the requirements established in paragraph (1), consider the following factors:

''(A) To what extent the applicant has the capacity to broaden the scope of research and research training programs of the applicant by promoting—

''(i) interdisciplinary research;

''(ii) research on emerging technologies, including those involving novel

analytical techniques or computational methods; or

''(iii) other novel research mechanisms or programs.

''(B) To what extent the applicant has broadened the scope of research and research training programs of qualified institutions by promoting genomic research with an emphasis on interdisciplinary research, including research related to pediatric investigations.

''(3) INSTITUTIONS OF EMERGING EXCELLENCE.—Of the amounts appropriated under subsection (i) for a fiscal year, the Director of the Center shall make available 25 percent for grants under subsection (a) to applicants that, in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

''(A) The applicant has a plan for research or training advancement and possesses the ability to carry out the plan.

''(B) The applicant carries out research and research training programs that have a special relevance to a problem, concern, or unmet health need of the United States.

''(C) The applicant has been productive in research or research development and training.

''(D) The applicant—

''(i) has been designated as a center of excellence under section 739;

''(ii) is located in a geographic area a significant percentage of whose population has a health-status deficit, and the applicant provides health services to such population; or

''(iii) is located in a geographic area in which a deficit in health care technology, services, or research resources may adversely affect health status of the population of the area in the future, and the applicant is carrying out activities with respect to protecting the health status of such population.

''(d) REQUIREMENT OF APPLICATION.—The Director of the Center may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

''(e) AMOUNT OF GRANT; PAYMENTS.—

''(1) AMOUNT.—The amount of any grant awarded under subsection (a) shall be determined by the Director of the Center, except that such amount shall not exceed—

''(A) 50 percent of the necessary cost of the construction of a proposed facility as determined by the Director; or

''(B) in the case of a multipurpose facility, 40 percent of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

''(2) RESERVATION OF AMOUNTS.—On approval of any application for a grant under subsection (a), the Director of the Center shall reserve, from any appropriation available therefore, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of the Director of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amendment of

the application or on the revision of the estimated cost of construction of the facility.

''(3) EXCLUSION OF CERTAIN COSTS.—In determining the amount of any grant under this subsection (a), there shall be excluded from the cost of construction an amount equal to the sum of—

''(A) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by a grant authorized under this section; and

''(B) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

''(4) WAIVER OF LIMITATIONS.—The limitations imposed by paragraph (1) may be waived at the discretion of the Director for applicants meeting the conditions described in paragraphs (1) and (2) of subsection (c).

''(f) RECAPTURE OF PAYMENTS.—If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

''(1) the applicant or other owner of the facility shall cease to be a public or nonprofit private entity; or

''(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so); the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

''(g) NONINTERFERENCE WITH ADMINISTRATION OF ENTITIES.—Except as otherwise specifically provided in this section, nothing contained in this part shall be construed as authorizing any department, agency, officer, or employee of the United States to exercise any direction, supervision, or control over, or impose any requirement or condition with respect to the administration of any entity funded under this part.

''(h) GUIDELINES.—Not later than 6 months after the date of the enactment of this section, the Director of the Center, after consultation with the Advisory Council,

shall issue guidelines with respect to grants under subsection (a).

''(i) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section and section 481B, there are authorized to be appropriated $150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''.

SEC. 1503. CONSTRUCTION PROGRAM FOR NATIONAL PRIMATE RESEARCH CENTER.

Subpart 1 of part E of title IV of the Public Health Service Act, as amended by section 1502 of this Act, is amended by adding at the end the following new section:

''CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH ON PRIMATES

''SEC. 481B. (a) The Director of the National Institutes of Health, acting through the Director of the National Center for Research Resources, may award grants and contracts to public or nonprofit private entities to construct, renovate, or otherwise improve such regional centers.

''(b) The Director of NIH may not make a grant or enter into a contract under subsection (a) unless the applicant for such assistance agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such subsection, to make available (directly or through donations from public or private entities) non-

Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $4 of Federal funds provided in such assistance.

''(c) The Secretary may reserve not more than $7,000,000 of the amounts appropriated under section 481A(i) for each fiscal year to carry out this section.''.

Subtitle B—National Center for Nursing Research

SEC. 1511. REDESIGNATION OF NATIONAL CENTER FOR NURSING RESEARCH AS NATIONAL INSTITUTE OF NURSING RESEARCH.

(a) IN GENERAL.—Subpart 3 of part E of title IV of the Public Health Service Act (42 U.S.C. 287c et seq.) is amended—

(1) in section 483—

(A) in the heading for the section, by striking ''CENTER'' and inserting ''INSTITUTE''; and

(B) by striking ''The general purpose'' and all that follows through ''is'' and inserting the following: ''The general purpose of the National Institute of Nursing Research (hereafter in this subpart referred to as the 'Institute') is'';

(2) in section 484, by striking ''Center'' each place such term appears and inserting ''Institute'';

(3) in section 485—

(A) in subsection (a), in each of paragraphs (1) through (3), by striking ''Center'' each place such term appears and inserting ''Institute'';

(B) in subsection (b)—

(i) in paragraph (2)(A), by striking ''Center'' and inserting ''Institute''; and

(ii) in paragraph (3)(A), in the first sentence, by striking ''Center'' and inserting ''Institute''; and

(C) in subsections (d) through (g), by striking ''Center'' each place such term appears and inserting ''Institute''; and

(4) in section 485A (as redesignated by section 141(a)(1) of this Act), by striking ''Center'' each place such term appears and inserting ''Institute''.

(b) CONFORMING AMENDMENTS.—

(1) ORGANIZATION OF NATIONAL INSTITUTE OF HEALTH.—Section 401(b) of the Public Health Service Act (42 U.S.C. 281(b)) is amended—

(A) in paragraph (1), by adding at the end the following new subparagraph:

''(Q) The National Institute of Nursing Research.''; and

(B) in paragraph (2), by striking subparagraph (D).

(2) TRANSFER OF STATUTORY PROVISIONS.—Sections 483 through 485A of the Public Health Service Act, as amended by subsection (a) of this section—

(A) are transferred to part C of title IV of such Act;

(B) are redesignated as sections 464V through 464Y of such part; and

(C) are inserted, in the appropriate sequence, at the end of such part.

(3) HEADING FOR NEW SUBPART.—Title IV of the Public Health Service Act, as amended by the preceding provisions of this section, is amended—

(A) in part C, by inserting before section 464V the following new heading:

''Subpart 17—National Institute of Nursing Research'';

and

(B) by striking the heading for subpart 3 of part E.

(4) CROSS-REFERENCES.—Title IV of the Public Health Service Act, as amended by the preceding provisions of this section, is amended in subpart 17 of part C—

(A) in section 464W, by striking ''section 483'' and inserting ''section 464V'';

(B) in section 464X(g), by striking ''section 486'' and inserting ''section 464Y''; and

(C) in section 464Y, in the last sentence, by striking ''section 485(g)'' and inserting ''section 464X(g)''.

SEC. 1512. STUDY ON ADEQUACY OF NUMBER OF NURSES.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the National Institute of Nursing Research and in collaboration with the Division of Nursing of the Health Resources and Services Administration, shall enter into a contract with a public or nonprofit private entity to conduct a study for the purpose of determining whether and to what extent there is a need for an increase in the number of nurses in hospitals and nursing homes in order to promote the quality of patient care and reduce the incidence among nurses of work-related injuries and stress.

(b) NATIONAL ACADEMY OF SCIENCES.—The Secretary shall request the National Academy of Sciences to enter into the contract under subsection (a) to conduct the study described in such subsection. If such Institute declines to conduct the study, the Secretary shall carry

out such subsection through another public or nonprofit private entity.

(c) DEFINITIONS.—For purposes of this section:

(1) The term ''nurse'' means a registered nurse, a licensed practical nurse, a licensed vocational nurse, and a nurse assistant.

(2) The term ''Secretary'' means the Secretary of Health and Human Services.

(d) REPORTS.—The Secretary shall ensure that, not later than 18 months after the date of enactment of this Act, an interim report describing the preliminary findings of the study conducted under this section will be issued, and not later than 3 years after such date of enactment, a final report shall be issued. Such reports shall be submitted to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate.

Subtitle C—National Center for Human Genome Research

SEC. 1521. PURPOSE OF CENTER.

Title IV of the Public Health Service Act, as amended by sections 141(a)(1) and 1611(b)(1)(B) of this Act, is amended—

(1) in section 401(b)(2), by adding at the end the following new subparagraph:

''(D) The National Center for Human Genome Research.''; and

(2) in part E, by adding at the end the following new subpart:

''Subpart 4—National Center for Human Genome Research

''PURPOSE OF THE CENTER

''SEC. 485B. (a) The general purpose of the National Center for Human Genome Research (hereafter in this subpart referred to as the 'Center') is to characterize the structure and function of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

''(1) planning and coordinating the research goal of the genome project;

''(2) reviewing and funding research proposals;

''(3) developing training programs;

''(4) coordinating international genome research;

''(5) communicating advances in genome science to the public; and

''(6) reviewing and funding proposals to address the ethical and legal issues associated with the genome project.

''(b)(1) Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the Center is authorized to make available not less than 5 percent for carrying out paragraph (6) of such subsection.

''(2) With respect to providing funds under subsection (a)(6) for proposals to address the ethical and legal issues, including the issuing of patents, associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Director of the Center certifies to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has determined that an insufficient number of such proposals meet the applicable requirements of sections 491 and 492.

''(3) In carrying out the provisions of paragraph (1), the Director of the Center shall consider proposals from qualified public and nonprofit academic or research facilities.''.

TITLE XVI—AWARDS AND TRAINING

Subtitle A—National Research Service Awards

SEC. 1601. REQUIREMENT REGARDING WOMEN AND INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.

Section 487(a) of the Public Health Service Act (42 U.S.C. 288(a)(4)) is amended by adding at the end the following paragraph:

''(4) The Secretary shall carry out paragraph (1) in a manner that will result in the recruitment of women, and members from underrepresented minority groups, into fields of biomedical or behavioral research and in the provision of research training to women and such individuals.''.

SEC. 1602. SERVICE PAYBACK REQUIREMENTS.

Paragraph (2) of section 487(c) of the Public Health Service Act (42 U.S.C. 288(c)(2)) is amended to read as follows:

''(2)(A) For the initial year for which an individual receives a National Research Service Award for the conduct of postdoctoral training or research, such individual shall engage in one year of health research or teaching or any combination thereof which is in accordance with

the usual patterns of academic employment, or complete a second year of training or research under such Award.

''(B) Service obligations for National Research Service Awards that are less than 12 months may be satisfied—

''(i) by the conduct of health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment for a period of time equal to the amount of time under the Award; or

''(ii) by reimbursing the Federal Government for the amounts provided to such individual under the Award.''.

Subtitle B—Acquired Immune Deficiency Syndrome

SEC. 1611. LOAN REPAYMENT PROGRAM.

Section 487A of the Public Health Service Act (42 U.S.C. 288–1) is amended to read as follows:

''LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

''SEC. 487A. (a) IN GENERAL.—

''(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct, as employees

of the National Institutes of Health, research with respect to acquired immune deficiency syndrome in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of such health professionals.

''(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

''(A) has a substantial amount of educational loans relative to income; and

''(B)(i) was not employed at the National Institutes of Health during the 1-year period preceding the date of the enactment of the Health Professions Reauthorization Act of 1988; or

''(ii) agrees to serve as an employee of such Institutes for purposes of paragraph (1) for a period of not less than 3 years.''.

''(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply

to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

''(c) FUNDING; REIMBURSABLE TRANSFERS.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

''(2) TRANSFERS FOR RELATED PROGRAM.—The Commissioner of Food and Drugs may carry out for the Food and Drug Administration a program similar to the program established in subsection (a), which program shall be carried out with respect to the review of applications concerning acquired immune deficiency syndrome that are submitted to such Commissioner. From the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may transfer amounts to the Commissioner for the purpose of carrying out such program. The Commissioner shall provide a reimbursement to the Secretary for the amount so transferred, and the reimbursement shall be available only for the program established in subsection (a). Any transfer and

reimbursement made for purposes of this paragraph for a fiscal year shall be completed by April 1 of such year.''.

Subtitle C—Loan Repayment for Research Generally

SEC. 1621. ESTABLISHMENT OF PROGRAM.

Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1002 of this Act, is amended by inserting after section 487B the following new section:

''LOAN REPAYMENT PROGRAM FOR RESEARCH GENERALLY

''SEC. 487C. (a) IN GENERAL.—

''(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of such health professionals.

''(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional

pursuant to paragraph (1) unless such professional—

''(A) has a substantial amount of educational loans relative to income; and

''(B)(i) was not employed at the National Institutes of Health during the 1-year period preceding the date of the enactment of the Health Professions Reauthorization Act of 1988; or

''(ii) agrees to serve as an employee of such Institutes for purposes of paragraph (1) for a period of not less than 3 years.''.

''(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

''(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section other than with respect to acquired immune deficiency syndrome, there are

authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.''.

Subtitle D—Scholarship and Loan Repayment Programs Regarding Professional Skills Needed by Certain Agencies

SEC. 1631. ESTABLISHMENT OF PROGRAMS FOR NATIONAL INSTITUTES OF HEALTH.

Part G of title IV of the Public Health Service Act, as redesignated by section 141(a)(2) of this Act and as amended by section 1621 of this Act, is amended by inserting after section 487C the following new sections:

''UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY NATIONAL RESEARCH INSTITUTES

''SEC. 487D. (a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH, may carry out a program of entering into contracts with individuals described in paragraph (2) under which—

''(A) the Director of NIH agrees to provide to the individuals scholarships for pursuing, as undergraduates at accredited institutions of higher education, academic programs appro-

priate for careers in professions needed by the National Institutes of Health; and

''(B) the individuals agree to serve as employees of the National Institutes of Health, for the period described in subsection (c), in positions that are needed by the National Institutes of Health and for which the individuals are qualified.

''(2) INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.—The individuals referred to in paragraph (1) are individuals who—

''(A) are enrolled or accepted for enrollment as full-time undergraduates at accredited institutions of higher education; and

''(B) are from minority groups that are underrepresented in the fields of biomedical or behavioral research.

''(b) FACILITATION OF INTEREST OF STUDENTS IN CAREERS AT NATIONAL INSTITUTES OF HEALTH.—In providing employment to individuals pursuant to contracts under subsection (a)(1), the Director of NIH shall carry out activities to facilitate the interest of the individuals in pursuing careers as employees of the National Institutes of Health.

''(c) PERIOD OF OBLIGATED SERVICE.—

''(1) DURATION OF SERVICE.—For purposes of subparagraph (B) of subsection (a)(1), the period of service for which an individual is obligated to serve as an employee of the National Institutes of Health is 12 months for each academic year for which the scholarship under such subsection is provided.

''(2) SCHEDULE FOR SERVICE.—

''(A) Subject to subparagraph (B), the Director of NIH may not provide a scholarship under subsection (a) unless the individual applying for the scholarship agrees that—

''(i) the individual will serve as an employee of the National Institutes of Health full-time for not less than 10 consecutive weeks of each year during which the individual is attending the educational institution involved and receiving such a scholarship;

''(ii) the period of service as such an employee that the individual is obligated to provide under clause (i) is in addition to the period of service as such an employee that the individual is obligated to provide under subsection (a)(1)(B); and

''(iii) not later than 60 days after obtaining the educational degree involved, the individual will begin serving full-time as such an employee in satisfaction of the period of service that the individual is obligated to provide under subsection (a)(1)(B).

''(B) The Director of NIH may defer the obligation of an individual to provide a period of service under subsection (a)(1)(B), if the Director determines that such a deferral is appropriate.

''(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO APPOINTMENT AND COMPENSATION.—For any period in which an individual provides service as an employee of the National Institutes of Health in satisfaction of the obligation of the individual under subsection (a)(1)(B) or paragraph (2)(A)(i), the individual may be appointed as such an employee without regard to the provisions of title 5, United States Code, relating to appointment and compensation.

''(d) PROVISIONS REGARDING SCHOLARSHIP.—

''(1) APPROVAL OF ACADEMIC PROGRAM.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless—

''(A) the individual applying for the scholarship has submitted to the Director a proposed academic program for the year and the Director has approved the program; and

''(B) the individual agrees that the program will not be altered without the approval of the Director.

''(2) ACADEMIC STANDING.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless the individual applying for the scholarship agrees to maintain an acceptable level of academic standing, as determined by the educational institution involved in accordance with regulations issued by the Secretary.

''(3) LIMITATION ON AMOUNT.—The Director of NIH may not provide a scholarship under subsection (a) for an academic year in an amount exceeding $20,000.

''(4) AUTHORIZED USES.—A scholarship provided under subsection (a) may be expended only for tuition expenses, other reasonable educational ex-

penses, and reasonable living expenses incurred in attending the school involved.

''(5) CONTRACT REGARDING DIRECT PAYMENTS TO INSTITUTION.—In the case of an institution of higher education with respect to which a scholarship under subsection (a) is provided, the Director of NIH may enter into a contract with the institution under which the amounts provided in the scholarship for tuition and other educational expenses are paid directly to the institution. Payments to the institution under the contract may be made without regard to section 3324 of title 31, United States Code.

''(e) PENALTIES FOR BREACH OF SCHOLARSHIP CONTRACT.—The provisions of section 338E shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

''(f) REQUIREMENT OF APPLICATION.—The Director of NIH may not provide a scholarship under subsection (a) unless an application for the scholarship is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

''(g) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for scholarships under this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

''LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS FROM DISADVANTAGED BACKGROUNDS

''SEC. 487E. (a) IMPLEMENTATION OF PROGRAM.—

''(1) IN GENERAL.—Subject to section 487(a)(1)(C), the Secretary, acting through the Director of NIH may, subject to paragraph (2), carry out a program of entering into contracts with appropriately qualified health professionals who are from disadvantaged backgrounds under which such health professionals agree to conduct clinical research as employees of the National Institutes of Health in consideration of the Federal Government agreeing to pay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of the health professionals.

''(2) LIMITATION.—The Director of NIH may not enter into a contract with a health professional pursuant to paragraph (1) unless such professional has a substantial amount of education loans relative to income.

''(3) APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—Except to the extent inconsistent with this section, the provisions of sections 338C and 338E shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

''(b) AVAILABILITY OF AUTHORIZATION OF APPROPRIATIONS.—Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.''.

SEC. 1632. FUNDING.

Section 487(a)(1) of the Public Health Service Act (42 U.S.C. 288(a)(1)) is amended—

(1) in subparagraph (A), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(C) provide contracts for scholarships and loan repayments in accordance with sections 487D and 487E, subject to providing not more than an aggre-

gate 50 such contracts during the fiscal years 1994 through 1996.''.

Subtitle E—Funding

SEC. 1641. AUTHORIZATION OF APPROPRIATIONS.

Section 487(d) of the Public Health Service Act (42 U.S.C. 288(d)) is amended—

(1) in the first sentence, by amending the sentence to read as follows: ''For the purpose of carrying out this section, there are authorized to be appropriated $400,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.''; and

(2) in paragraph (3)—

(A) by striking ''one-half of one percent'' each place such term appears and inserting ''1 percent''; and

(B) by striking ''780, 784, or 786'' and inserting ''747, 748, or 749''.

TITLE XVII—NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH

SEC. 1701. NATIONAL FOUNDATION FOR BIOMEDICAL RESEARCH.

Section 499 of the Public Health Service Act, as redesignated by section 121(b), is amended—

(1) in subsection (a), by striking ‘‘, except for’’ and all that follows through ‘‘Transfer Act’’;

(2) by redesignating subsections (c), (d), (e), (f), (g), (h), and (i) as subsections (d), (f), (g), (h), (i), (j), and (m), respectively;

(3) by striking subsection (b) and inserting in lieu thereof the following new subsections:

‘‘(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to support the National Institutes of Health in its mission, and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

‘‘(c) CERTAIN ACTIVITIES OF FOUNDATION.—

‘‘(1) IN GENERAL.—In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

‘‘(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel,

and other expenditures that are appropriate in supporting the endowed positions.

''(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses. The recipients of fellowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement of the Director of the National Institutes of Health and the Executive Director of the Foundation.

''(C) Supplementary programs to provide for—

''(i) scientists of other countries to serve in research capacities in the United States in association with the National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of Health or other public health offi-

cials in the United States to serve in such capacities in other countries, or both;

''(ii) the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

''(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

''(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

''(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

''(vi) the conduct of other activities to carry out and support the purpose described in subsection (b).

''(2) FEES.—The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

''(3) AUTHORITY OF FOUNDATION.—The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.'';

(4) in subsection (d) (as so redesignated)—

(A) in paragraph (1)—

(i) by striking ''members of the Foundation'' in subparagraph (A) and inserting ''appointed members of the Board'';

(ii) by striking ''Council'' in subparagraph (B) and inserting ''Board'';

(iii) by striking ''Council'' in subparagraph (C) and inserting ''Board''; and

(iv) by adding at the end thereof the following new subparagraphs:

''(D)(i) Not later than 30 days after the date of enactment of the National Institutes of Health Revitalization Act of 1993, the Director

of the National Institutes of Health shall convene a meeting of the ex officio members of the Board to—

''(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the bylaws of the Foundation; and

''(II) appoint the members of the Board in accordance with subparagraph (C).

''(ii) Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

''(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

''(F) No employee of the National Institutes of Health shall be appointed as a member of the Board.

''(G) The Board may, through amendments to the bylaws of the Foundation, provide

that the number of members of the Board shall be greater than the number specified in subparagraph (C).'';

(B) in paragraph (2)—

(i) by inserting ''(A)'' before ''The ex'';

(ii) by striking ''an appointed member of the Board to serve as the Chair'' and inserting ''an individual to serve as the initial Chairperson''; and

(iii) by adding at the end thereof the following new subparagraph:

''(B) Upon the termination of the term of service of the initial Chairperson of the Board, the appointed members of the Board shall elect a member of the Board to serve as the Chairperson of the Board.'';

(C) in paragraph (3)(A), by striking ''(2)(C)'' and inserting ''(1)(C)''; and

(D) by adding at the end thereof the following new paragraphs:

''(5) MEETINGS AND QUORUM.—A majority of the members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

''(6) CERTAIN BYLAWS.—

''(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

''(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

''(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

''(iii) Policies for the conduct of the general operations of the Foundation.

''(iv) Policies for writing, editing, printing, publishing, and vending of books and other materials.

''(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

''(i) reflect unfavorably upon the ability of the Foundation or the National Institutes of Health to carry out its responsibilities or official duties in a fair and objective manner; or

''(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.'';

(5) in subsection (i) (as so redesignated)—

(A) by inserting '', and define the duties of the officers and employees'' before the semicolon in paragraph (4);

(B) by striking paragraph (5);

(C) by redesignating paragraphs (6) through (14), as paragraphs (5) through (13), respectively;

(D) by striking paragraph (8) (as so redesignated), and inserting the following new paragraph:

''(8) establish a process for the selection of candidates for positions under subsection (c);''

(E) by inserting ''solicit'' after the paragraph designation in paragraph (11) (as so redesignated);

(F) by striking ''Executive'' in paragraph (12) (as so redesignated);

(G) by striking ''and'' at the end of paragraph (13) (as so redesignate); and

(H) by inserting after paragraph (13) (as so redesignated), the following new paragraph:

''(14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Director considers appropriate to conduct the activities of the Foundation; and'';

(6) by inserting after subsection (j) (as so redesignated), the following new subsections:

''(k) GENERAL PROVISIONS.—

''(1) FOUNDATION INTEGRITY.—The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct (including those developed under subsection (d)(2)(B)(i)(II)), financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

''(2) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(2)(B)(i)(II)) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

''(3) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

''(A) provide for annual audits of the financial condition of the Foundation; and

''(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

''(4) REPORTS.—

''(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation.

''(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include

a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

''(C) The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

''(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

''(5) SERVICE OF FEDERAL EMPLOYEES.—Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its function, so long as the employees do not direct or control Foundation activities.

''(6) RELATIONSHIP WITH EXISTING ENTITIES.—The Foundation may, pursuant to appropriate agreements, merge with, acquire, or use the resources of existing nonprofit private corporations with missions similar to the purposes of the Founda-

tion, such as the Foundation for Advanced Education in the Sciences.

''(7) INTELLECTUAL PROPERTY RIGHTS.—The Board shall adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

''(8) NATIONAL INSTITUTES OF HEALTH AMENDMENTS OF 1990.—The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101-613) and the amendments made by such Act, shall not be nullified by the enactment of this section.

''(9) LIMITATION OF ACTIVITIES.—The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.

''(l) DUTIES OF THE DIRECTOR.—

''(1) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal

Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the Director of the National Institutes of Health, or the designee of such Director, has been executed specifying that the individual shall be subject to such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of the National Institutes of Health determines is appropriate.

''(2) SUPPORT SERVICES.—The Director of the National Institutes of Health may provide facilities, utilities and support services to the Foundation if it is determined by the Director to be advantageous to the research programs of the National Institutes of Health.'';

(7) in subsection (m) (as so redesignated)—

(A) by striking ''$200,000'' each place that such appears and inserting ''$500,000''; and

(B) by striking ''1995'' in paragraph (1) and inserting ''1996''; and

(8) by adding at the end thereof the following new subsections:

''(n) LIMITATION.—The Secretary shall ensure that no extramural funds made available by the National Institutes of Health are provided to the Foundation or for activities provided for under subparagraphs (A) and (B) of subsection (c)(1).

''(o) REPORT ON ADEQUACY OF COMPLIANCE.—

''(1) IN GENERAL.—With respect to the mission and function of the Foundation, the Comptroller General of the United States shall conduct an audit to determine—

''(A) whether the Foundation is in compliance with the guidelines established under this section; and

''(B) whether the procedures utilized under this section are adequate to prevent conflicts of interest involving the Foundation, the employees of the Foundation or members of the Board of the Foundation.

''(2) REPORT.—Not later than 18 months after the date on which the Foundation is incorporated, the Comptroller General of the United States shall complete the audit required under paragraph (1) and prepare and submit to the Committee on En-

ergy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings made with respect to such audit.''.

TITLE XVIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

SEC. 1801. REVISION AND EXTENSION OF VARIOUS PROGRAMS.

(a) AMENDMENTS.—Title XXIII of the Public Health Service Act (42 U.S.C. 300cc et seq.) is amended—

(1) in section 2304(c)(1)—

(A) in the matter preceding subparagraph (A), by inserting after ''Director of such Institute'' the following: ''(and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate)''; and

(B) in subparagraph (A), by inserting before the semicolon the following: '', including recommendations on the projects of research with respect to diagnosing immune deficiency and with respect to predicting, diagnosing, pre-

venting, and treating cancers, opportunistic infections, and infectious diseases'';

(2) in section 2311(a)(1), by inserting before the semicolon the following: '', including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating cancers, opportunistic infections, and infectious diseases'';

(3) in section 2315(a)(2), by striking ''international research'' and all that follows and inserting ''international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome and opportunistic infections.'';

(4) in section 2318—

(A) in subsection (a)(1)—

(i) by inserting after ''The Secretary'' the following: '', acting through the Director of the National Institutes of Health and after consultation with the Administrator for Health Care Policy and Research,''; and

(ii) by striking ''syndrome'' and inserting ''syndrome, including treatment and prevention of HIV infection and related conditions among women''; and

(B) in subsection (e), by striking ''1991.'' and inserting the following: ''1991, and such sums as may be necessary for each of the fiscal years 1994 through 1996.'';

(5) in section 2320(b)(1)(A), by striking ''syndrome'' and inserting ''syndrome and the natural history of such infection'';

(6) in the part heading for part D, by striking ''DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH'' and inserting ''OFFICE OF AIDS RESEARCH'';

(7) in section 2351—

(A) by redesignating subsections (a), (b) and (c) as subsections (c), (d) and (e), respectively;

(B) by inserting after the section heading the following new subsections:

''(a) IN GENERAL.—In carrying out research with respect to acquired immune deficiency syndrome, the Secretary, acting through the Director of the National Institutes of Health—

''(1) shall establish an office to be known as the Office of AIDS Research, which Office shall be headed by a Director who shall—

''(A) be appointed by the Secretary;

''(B) be determined by the Secretary to be an individual who is an outstanding scientist and a highly skilled administrator;

''(C) report directly to the Director of the National Institutes of Health; and

''(D) be the primary Federal official responsible for the conduct of AIDS-related research at the National Institutes of Health; and

''(2) shall provide administrative support and support services to the Director of such Office and shall ensure that such support takes maximum advantage of existing administrative structures at the institutes, centers and divisions of the National Institutes of Health to the fullest extent practicable.

''(b) ACTIVITIES OF THE OFFICE OF AIDS RESEARCH.—

''(1) IN GENERAL.—The Secretary, acting through the director of the Office of AIDS Research, shall ensure that AIDS research activities are coordinated across and throughout the institutes, cen-

ters, and divisions of the National Institutes of Health.

''(2) GENERAL DUTIES.—The Director of the Office of AIDS Research shall, based upon a strategic plan as defined in paragraph (3), develop and oversee the implementation of a scientifically justified budget for AIDS-related research at the National Institutes of Health and coordinate all AIDS-related research activities conducted at the institutes, centers, and divisions of the National Institutes of Health, and conduct evaluations on all such programs.

''(3) STRATEGIC PLAN.—

''(A) DEVELOPMENT.—The Director of the Office of AIDS Research shall, based on the advice of the directors of the institutes, centers, and divisions of the National Institutes of Health, and in consultation with the advisory council established in paragraph (5) and the coordinating groups established in subparagraph (B), develop and oversee the implementation of a comprehensive, long-range plan for the conduct and support of such research by the institutes, centers and divisions of the National In-

stitutes of Health. Such plan shall be updated annually, and shall—

''(i) determine the appropriate overall balance between basic and applied research and between intramural and extramural research;

''(ii) determine and prioritize among critical scientific AIDS-related questions;

''(iii) based upon such determinations, specify the broad short and long range objectives to be achieved, and provide an estimate of the resources needed to achieve such objectives;

''(iv) evaluate the sufficiency of existing AIDS research programs to meet such objectives, and establish evaluation criteria, timelines and objectives for future program evaluation activities; and

''(v) make recommendations for changes and necessary resource allocation in and among such programs.

''(B) COORDINATING GROUPS.—The Director of the Office of AIDS Research shall establish AIDS coordinating groups for each research discipline within the AIDS research pro-

gram, composed of representatives of relevant agencies of the National Institutes of Health and qualified extramural scientists, to evaluate and assess the efforts of the AIDS Research Program at the National Institutes of Health, to advise on the development of the strategic plan described in subparagraph (A), and to determine the extent to which such efforts are in accordance with such strategic plan.

''(4) COORDINATION.—The Director of the Office of AIDS Research shall act as the primary Federal official with responsibility for overseeing all AIDS-related research efforts undertaken by the National Institutes of Health, and

''(A) shall serve to represent the National Institutes of Health AIDS Research Program at all relevant Executive branch task forces and committees; and

''(B) shall maintain communications with all relevant Public Health Service agencies and with various other departments of the Federal Government, to ensure the timely transmission of information concerning advances in AIDS-related research and the clinical treatment of AIDS and its related conditions, between these

various agencies for dissemination to affected communities and health care providers.

''(5) ADVISORY COUNCIL.—

''(A) ESTABLISHMENT.—The Secretary shall, consistent with section 406, establish an advisory council to be known as the Office of AIDS Research Advisory Council (hereafter referred to as the 'Council'), which shall serve to replace the AIDS Program Advisory Committee which is operating on the date of enactment of this subsection.

''(B) COMPOSITION.—The Council shall be composed of biomedical, behavioral, and social scientists, and representatives of diverse HIV affected communities, and shall be appointed by the Secretary.

''(C) AUTHORITY.—The Council shall—

''(i) advise the Director of the Office of AIDS Research and make recommendations concerning the development of the AIDS-related research budget, and the development and implementation of the strategic plan for AIDS-related research at the National Institutes of Health;

''(ii) provide the second level of peer review for awards made directly from the Office of AIDS Research from the discretionary fund described in paragraph (7); and

''(iii) carry out such other activities determined appropriate by the Director of the Office of AIDS Research.

''(6) BUDGETARY AUTHORITY.—The Director of the Office of AIDS Research shall—

''(A) in accordance with the strategic plan established under paragraph (3), in consultation with the Council, and based on budget requests and additional advice from the directors of the institutes, centers and divisions of the National Institutes of Health, prepare and submit directly to the President for review and transmittal to Congress, an annual, scientifically justified budget estimate for AIDS-related research conducted within the agencies of the National Institutes of Health, after reasonable opportunity for comment (but without change) by the Secretary and the Director of the National Institutes of Health, which shall include the amount of funds required (as requested by the

directors of such institutes, centers and divisions) for—

''(i) the continued funding of the commitment base (ongoing program initiatives) at the sole discretion of the directors of such institutes, centers and divisions; and

''(ii) the funding of new and competing program initiatives through such institutes, centers and divisions, at the discretion of the Director of the Office of AIDS Research;

''(B) receive from the President and the Office of Management and Budget directly all AIDS-related research funds appropriated by Congress for transfer to, and obligation and expenditure by, the institutes, centers and divisions of the National Institutes of Health in accordance with the budget delineated under clauses (i) and (ii) of subparagraph (A); and

''(C) distribute AIDS research funding to the various institutes, centers, and divisions of the National Institutes of Health in accordance with the budget delineated under clauses (i) and (ii) of subparagraph (A).

The provisions of this paragraph shall become effective in the fiscal year following the submission of the consolidated AIDS budget.

''(7) DISCRETIONARY FUND.—

''(A) AVAILABILITY OF FUNDS.—The Secretary shall ensure that not to exceed 25 percent of the funds available in excess of the amount of baseline AIDS research spending during the previous fiscal year, be made available to the Director of the Office of AIDS Research for the establishment of an AIDS research discretionary fund.

''(B) USE.—The Director of the Office of AIDS Research, in consultation with the advisory council established under paragraph (5), shall use amounts in the AIDS research discretionary fund, either through the institutes, centers and divisions of the National Institutes of Health or grants made directly by the Office of AIDS Research, to—

''(i) fund emergency AIDS research programs;

''(ii) fund programs for the conduct of research aimed at filling gaps that exist in existing research programs;

''(iii) conduct conferences, convene committees, hold meetings or carry out other activities determined appropriate by the Director.

''(C) REDUCTION IN ADMINISTRATIVE IMPEDIMENTS.—Notwithstanding any other provision of law relating to the number of individuals who may be employed as full-time equivalent individuals, with respect to the number of full-time equivalent individuals so employed, the Director of the Office of AIDS Research shall be permitted to authorize the employment of such full-time equivalent individuals to perform AIDS-related research through the institutes, centers and divisions of the National Institutes of Health as described in clauses (i) and (ii) of subparagraph (B) and subject to appropriations.'';

(C) in subsection (c) (as so redesignated)—

(i) by striking the subsection designation and all that follows through paragraph (1) and inserting the following:

''(c) OTHER DUTIES.—The director of the office—

'';

(ii) by redesignating paragraphs (2) through (8) as paragraphs (1) through (7), respectively;

(iii) by striking ''for the appropriate national research institute of the National Institutes of Health'' in paragraph (4) (as so redesignated); and

(iv) by inserting ''cannot reasonably be accomplished within the United States and'' after ''if such research'' in paragraph (4)(A) (as so redesignated); and

(D) by adding at the end thereof the following new subsection:

''(f) EVALUATION AND REPORT.—

''(1) EVALUATION.—Not later than 5 years after the date of enactment of this Act, the Secretary shall conduct an evaluation to—

''(A) determine the effect of this section on the planning and coordination of the AIDS research programs at the institutes, centers and divisions of the National Institutes of Health;

''(B) evaluate the extent to which this section has eliminated the duplication of administrative resources among such institutes, centers and divisions; and

''(C) provide recommendations concerning future alterations with respect to this section.

''(2) REPORT.—Not later than 1 year after the date on which the evaluation is commenced under paragraph (1), the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the results of such evaluation.'';

(8) in section 2361, by striking ''For purposes'' and all that follows and inserting the following:

''For purposes of this title:

''(1) The term 'infection', with respect to the etiologic agent for acquired immune deficiency syndrome, includes cancers, opportunistic infections, and infectious diseases and any other conditions arising from infection with such etiologic agent.

''(2) The term 'treatment', with respect to the etiologic agent for acquired immune deficiency syndrome, includes primary and secondary prophylaxis.'';

(9) in section 2315(f), by striking ''there are authorized'' and all that follows and inserting ''there are authorized to be appropriated such sums as may be necessary for each fiscal year.'';

(10) in section 2320(e)(1), by striking ''there are authorized'' and all that follows and inserting ''there are authorized to be appropriated such sums as may be necessary for each fiscal year.''; and

(11) in section 2341(d), by striking ''there are authorized'' and all that follows and inserting ''there are authorized to be appropriated such sums as may be necessary for each fiscal year.''.

TITLE XIX—STUDIES

SEC. 1901. ACQUIRED IMMUNE DEFICIENCY SYNDROME.

(a) CERTAIN DRUG-RELEASE MECHANISMS.—

(1) The Secretary of Health and Human Services shall, subject to paragraph (2), enter into a contract with a public or nonprofit private entity to conduct a study for the purpose of determining, with respect to acquired immune deficiency syndrome, the impact of parallel-track drug-release mechanisms on public and private clinical research, and on the activities of the Commissioner of Food and Drugs regarding the approval of drugs.

(2) The Secretary of Health and Human Services shall request the Institute of Medicine of the National Academy of Sciences to enter into the contract under paragraph (1) to conduct the study described in such paragraph. If such Institute declines

to conduct the study, the Secretary shall carry out paragraph (1) through another public or nonprofit private entity.

(b) THIRD-PARTY PAYMENTS REGARDING CERTAIN CLINICAL TRIALS.—The Secretary of Health and Human Services shall conduct a study for the purpose of—

(1) determining the policies of third-party payors regarding the payment of the costs of appropriate health services that are provided incident to the participation of individuals as subjects in clinical trials conducted in the development of drugs with respect to acquired immune deficiency syndrome; and

(2) developing recommendations regarding such policies.

(c) ADVISORY COMMITTEES.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study for the purpose of determining—

(1) whether the activities of the various advisory committees established in the National Institutes of Health regarding acquired immune deficiency syndrome are being coordinated sufficiently; and

(2) whether the functions of any of such advisory committees should be modified in order to achieve greater efficiency.

(d) VACCINES FOR HUMAN IMMUNODEFICIENCY VIRUS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the National Institutes of Health, shall develop a plan for the appropriate inclusion of HIV-infected women, including pregnant women, HIV-infected infants, and HIV-infected children in studies conducted by or through the National Institutes of Health concerning the safety and efficacy of HIV vaccines for the treatment and prevention of HIV infection. Such plan shall ensure the full participation of other Federal agencies currently conducting HIV vaccine studies and require that such studies conform fully to the requirements of part 46 of title 45, Code of Federal Regulations.

(2) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a re-

port concerning the plan developed under paragraph (1).

(3) IMPLEMENTATION.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall implement the plan developed under paragraph (1), including measures for the full participation of other Federal agencies currently conducting HIV vaccine studies.

(4) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

SEC. 1902. MALNUTRITION IN THE ELDERLY.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the National Institute on Aging, coordinating with the Agency for Health Care Policy and Research and, to the degree possible, in consultation with the head of the National Nutrition Monitoring System established under section 1428 of the Food and Agriculture Act of 1977 (7 U.S.C. 3178), shall conduct a 3-year nutrition

screening and intervention activities study of the elderly.

(2) EFFICACY AND COST-EFFECTIVENESS OF NUTRITION SCREENING AND INTERVENTION ACTIVITIES.—In conducting the study, the Secretary shall determine the efficacy and cost-effectiveness of nutrition screening and intervention activities conducted in the elderly health and long-term care continuum, and of a program that would institutionalize nutrition screening and intervention activities. In evaluating such a program, the Secretary shall determine—

(A) if health or quality of life is measurably improved for elderly individuals who receive routine nutritional screening and treatment;

(B) if federally subsidized home or institutional care is reduced because of increased independence of elderly individuals resulting from improved nutritional status;

(C) if a multidisciplinary approach to nutritional care is effective in addressing the nutritional needs of elderly individuals; and

(D) if reimbursement for nutrition screening and intervention activities is a cost-effective

approach to improving the health status of elderly individuals.

(3) POPULATIONS.—The populations of elderly individuals in which the study will be conducted shall include populations of elderly individuals who are—

(A) living independently, including—

(i) individuals who receive home and community-based services or family support;

(ii) individuals who do not receive additional services and support;

(iii) individuals with low incomes; and

(iv) individuals who are minorities;

(B) hospitalized, including individuals admitted from home and from institutions; and

(C) institutionalized in residential facilities such as nursing homes and adult homes.

(b) MALNUTRITION STUDY.—The Secretary, acting through the National Institute on Aging, shall conduct a 3-year study to determine the extent of malnutrition in elderly individuals in hospitals and long-term care facilities and in elderly individuals who are living independently.

(c) REPORT.—The Secretary shall submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives containing the findings resulting from the studies described in subsections (a) and (b), including a determination regarding whether a program that would institutionalize nutrition screening and intervention activities should be adopted, and the rationale for the determination.

(d) ADVISORY PANEL.—

(1) ESTABLISHMENT.—The Secretary, acting through the Director of the National Institute on Aging, shall establish an advisory panel that shall oversee the design, implementation, and evaluation of the studies described in subsections (a) and (b).

(2) COMPOSITION.—The advisory panel shall include representatives appointed for the life of the panel by the Secretary from the Health Care Financing Administration, the Social Security Administration, the National Center for Health Statistics, the Administration on Aging, the National Council on the Aging, the American Dietetic Association, the American Academy of Family Physicians, and such other agencies or organizations as the Secretary determines to be appropriate.

(3) COMPENSATION AND EXPENSES.—

(A) COMPENSATION.—Each member of the advisory panel who is not an employee of the Federal Government shall receive compensation for each day engaged in carrying out the duties of the panel, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.

(B) TRAVEL EXPENSES.—Each member of the advisory panel shall receive travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, for each day the member is engaged in the performance of duties away from the home or regular place of business of the member.

(4) DETAIL OF FEDERAL EMPLOYEES.—On the request of the advisory panel, the head of any Federal agency shall detail, without reimbursement, any of the personnel of the agency to the advisory panel to assist the advisory panel in carrying out its duties. Any detail shall not interrupt or otherwise af-

fect the civil service status or privileges of the Federal employee.

(5) TECHNICAL ASSISTANCE.—On the request of the advisory panel, the head of a Federal agency shall provide such technical assistance to the advisory panel as the advisory panel determines to be necessary to carry out its duties.

(6) TERMINATION.—Notwithstanding section 15 of the Federal Advisory Committee Act (5 U.S.C. App.), the advisory panel shall terminate 3 years after the date of enactment of this Act.

SEC. 1903. RESEARCH ACTIVITIES ON CHRONIC FATIGUE SYNDROME.

The Secretary of Health and Human Services shall, not later than May 1, 1993, and annually thereafter for the next 3 years, prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report that summarizes the research activities conducted or supported by the National Institutes of Health concerning chronic fatigue syndrome. Such report should include information concerning grants made, cooperative agreements or contracts entered into, intramural activities, research priorities and needs, and a plan to address such priorities and needs.

SEC. 1904. REPORT ON MEDICAL USES OF BIOLOGICAL AGENTS IN DEVELOPMENT OF DEFENSES AGAINST BIOLOGICAL WARFARE.

The Secretary of Health and Human Services, in consultation with other appropriate executive agencies, shall report to the House Energy and Commerce Committee and the Senate Labor and Human Resources Committee on the appropriateness and impact of the National Institutes of Health assuming responsibility for the conduct of all Federal research, development, testing, and evaluation functions relating to medical countermeasures against biowarfare threat agents. In preparing the report, the Secretary shall identify the extent to which such activities are carried out by agencies other than the National Institutes of Health, and assess the impact (positive and negative) of the National Institutes of Health assuming responsibility for such activities, including the impact under the Budget Enforcement Act and the Omnibus Budget Reconciliation Act of 1990 on existing National Institutes of Health research programs as well as other programs within the category of domestic discretionary spending. The Secretary shall submit the report not later than 12 months after the date of the enactment of this Act.

SEC. 1905. PERSONNEL STUDY OF RECRUITMENT, RETENTION AND TURNOVER.

(a) STUDY OF PERSONNEL SYSTEM.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study to review the retention, recruitment, vacancy and turnover rates of support staff, including firefighters, law enforcement, procurement officers, technicians, nurses and clerical employees, to ensure that the National Institutes of Health is adequately supporting the conduct of efficient, effective and high quality research for the American public. The Director of NIH shall work in conjunction with appropriate employee organizations and representatives in developing such a study.

(b) SUBMISSION TO CONGRESS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report containing the study conducted under subsection (a) together with the recommendations of the Secretary concerning the enactment of legislation to implement the results of such study.

SEC. 1906. PROCUREMENT.

(a) IN GENERAL.—The Director of the National Institutes of Health and the Administrator of the General Services Administration shall jointly conduct a study to develop a streamlined procurement system for the National Institutes of Health that complies with the requirements of Federal law.

(b) REPORT.—Not later than March 1, 1994, the officials specified in subsection (a) shall complete the study required in such subsection and shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.

SEC. 1907. REPORT CONCERNING LEADING CAUSES OF DEATH.

(a) REPORT.—The Secretary of Health and Human Services shall, not later than October 1, 1993, prepare a report that lists—

(1) the 20 illnesses that, in terms of mortality, number of years of expected life lost, and of number of preventable years of life lost, are the leading causes of death in the United States and the number of deaths from each such cause, the age-specific and age-adjusted death rates for each such cause, the death rate per 100,000 population for each such

cause, the percentage of change in cause specific death rates for each age group, and the percentage of total deaths for each such cause;

(2) the amount expended by the Department of Health and Human Services for research, prevention, and education with respect to each of the 20 illnesses described in paragraph (1) for the most recent year for which the actual expenditures are known;

(3) an estimate by the Secretary of the amount to be expended on research, prevention, and education with respect to each of the 20 illnesses described in paragraph (1) for the year for which the report is prepared; and

(4) with respect to the years specified in paragraphs (2) and (3), the percentage of the total of the annual expenditures for research, prevention, and education on the 20 illnesses described in paragraph (1) that are attributable to each illness.

(b) SUBMISSION TO CONGRESS.—The Secretary of Health and Human Services shall submit the report required under subsection (a), together with relevant budget information, to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Labor and Human

Resources and the Committee on Appropriations of the Senate.

SEC. 1908. RELATIONSHIP BETWEEN THE CONSUMPTION OF LEGAL AND ILLEGAL DRUGS.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and consider all existing relevant data and research concerning whether there is a relationship between an individual's receptivity to use or consume legal drugs and the consumption or abuse by the individual of illegal drugs. On the basis of such review, the Secretary shall determine whether additional research is necessary. If the Secretary determines additional research is required, the Secretary shall conduct a study of those subjects where the Secretary's review indicates additional research is needed, including, if necessary, a review of—

(1) the effect of advertising and marketing campaigns that promote the use of legal drugs on the public;

(2) the correlation of legal drug abuse with illegal drug abuse; and

(3) other matters that the Secretary determines appropriate.

(b) REPORT.—Not later than 12 months after the date of enactment of this Act, the Secretary shall prepare and submit, to the Committee on Energy and Commerce of the House of Representatives and Committee on Labor and Human Resources of the Senate, a report containing the results of the review conducted under subsection (b). If the Secretary determines additional research is required, no later than 2 years after the date of enactment of this Act, the Secretary shall prepare and submit, to the Committee on Energy and Commerce of the House of Representatives and Committee on Labor and Human Resources of the Senate, a report containing the results of the additional research conducted under subsection (b).

SEC. 1909. COST OF CARE IN LAST 6 MONTHS OF LIFE.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Agency for Health Care Policy and Research and, to the degree possible, in consultation with the Health Care Financing Administration, shall conduct a study, using the most recent National Medical Expenditure Survey database, to estimate the average amount of health care expenditures incurred during the last 6 months of life and during the last 3 months of life by—

(A) the population of individuals who are 65 years of age and older; and

(B) the total population, broken down based on noninstitutionalized and institutionalized populations.

(2) ELEMENTS OF STUDY.—The study conducted under paragraph (1) shall—

(A) be designed in a manner that will produce estimates of health care costs expended for health care provided to individuals during the last 3 and 6 months of life;

(B) be designed to produce estimates of such costs for the populations identified in subparagraphs (A) and (B) of paragraph (1);

(C) include a calculation of the estimated amount of total health care expenditures during such periods of time; and

(D) include a calculation of the estimate described in subparagraph (C)—

(i) as a percentage of the total national health care expenditures; and

(ii) for those age 65 years and over, as a percentage of the total Medicare expenditures for those age 65 years and over.

(b) REPORT.—Not later than 6 months after the date of enactment of this section, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report containing the findings resulting from the study described in subsection (a).

(c) 1996 NATIONAL MEDICAL EXPENDITURE SURVEY.—

(1) IN GENERAL.—The Secretary, acting through the Agency for Health Care Policy and Research, shall ensure that the 1996 National Medical Expenditure Survey is designed in a manner that will produce an estimate of the amount expended for health care provided to individuals during the last 3 and 6 months of life.

(2) POPULATIONS.—In designing the Survey under paragraph (1), the Secretary shall ensure that such Survey produces the data required under such paragraph for the population of individuals who are 65 years of age or older, broken down based on noninstitutionalized and institutionalized populations.

(d) EXPENDITURE STUDY.—

(1) IN GENERAL.—Not later than 6 months after that date of enactment of this section, the Secretary, acting through the Agency for Health Care Policy and Research, shall design a study to produce estimates of expenditures for health care provided to children who are less than 1 year of age during the last 3 and 6 months of life, and prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning such design. The Secretary shall ensure that such study is carried out not later than 2 years after the date on which such study is designed.

(2) REPORT.—Not later than 30 months after the date of enactment of this section, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the study described in paragraph (1).

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this subsection.

SEC. 1910. REDUCING ADMINISTRATIVE HEALTH CARE COSTS.

The Secretary of Health and Human Services, acting through the Agency for Health Care Policy and Research and, to the extent possible, in consultation with the Health Care Financing Administration, may fund research to develop a text-based standardized billing process, through the utilization of text-based information retrieval and natural language processing techniques applied to automatic coding and analysis of textual patient discharge summaries and other text-based electronic medical records, within a parallel general purpose (shared memory) high performance computing environment. The Secretary shall determine whether such a standardized approach to medical billing, through the utilization of the text-based hospital discharge summary as well as electronic patient records can reduce the administrative billing costs of health care delivery.

SEC. 1911. STUDY CONCERNING RADIOISOTOPES.

(a) STUDY.—The Secretary of Health and Human Services, in collaboration with the Secretary of Energy, shall, subject to the availability of funds, conduct a study concerning the use and availability of radioisotopes in the United States for medical (both diagnostic and therapeutic) uses in relationship to other uses.

(b) SUBJECT OF STUDY.—In carrying out the study under subsection (a), the Secretary shall—

(1) analyze the domestic isotope availability and production in the United States as it relates to medical (both diagnostic and therapeutic) needs;

(2) make recommendations concerning—

(A) isotope availability and production to meet domestic demand; and

(B) the need for additional production capacity.

(c) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on Energy and Natural Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the results of the study conducted under this section together with the recommendations developed in such study.

SEC. 1912. MEDICAL TECHNOLOGIES PRODUCTIVITY STUDY.

(a) FINDINGS.—Congress finds that—

(1)(A) the Congressional Budget Office, the General Accounting Office, and the Office of Technology Assessment have cited health care technology as a primary source of medical inflation; and

(B) data from the Office of Technology Assessment suggest that no more than one quarter of the 12 to 13 percent annual increase in health care expenditures, or an estimated 3 percent increase in such expenditures, is attributable to health care technology;

(2)(A) the 3 percent increase represents the maximum increase in such expenditures, because the Office of Technology Assessment arrives at the estimate by exclusion; and

(B) the increase attributable to health care technology may nevertheless amount to a direct increase of as much as $27,000,000,000 in health care costs in 1993 and an even greater indirect increase in such health care costs;

(3) one reason for the high increase in health care costs attributable to health care technology is that few incentives exist in the national research institutes of the National Institutes of Health to encourage the development of technology that improves the productivity of health care delivery; and

(4) since the National Institutes of Health is a major engine determining the direction of medical technology as well as basic biomedical research, it is appropriate, in the process of directing the medical

research and development resources of the National Institutes of Health, to provide incentives that encourage the development of technology to improve the productivity of health care delivery.

(b) STUDY.—The Secretary of Health and Human Services shall conduct a study concerning—

(1) methods by which to encourage the development of medical technologies that improve the productivity, and thereby reduce the cost, of health care delivery through changes in the scientific peer review process; and

(2) methods by which to reduce the costs of the production of new medical technologies and increase the availability of such technologies through changes in the scientific peer review process.

(c) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the study conducted under subsection (b). Such report shall contain the findings of the Secretary with respect to the study and the recommendations of the Secretary for the implementation of measures to encourage enhanced productivity of

medical technologies and increase the availability of such technologies through changes in the scientific peer review process. Such report shall also contain the steps that the Secretary proposes to implement the recommendations.

SEC. 1913. SENTINEL DISEASE CONCEPT STUDY.

(a) IN GENERAL.—The Director of the National Institutes of Health, in cooperation with the Agency for Toxic Substances and Disease Registry and the Centers for Disease Control and Prevention, may design and implement a pilot sentinel disease surveillance and follow-up system.

(b) PURPOSE.—The purpose of the study conducted under subsection (a) shall be to determine the applicability of and the difficulties associated with the implementation of the sentinel disease concept for identifying the relationship between the occupation of household members and the incidence of subsequent conditions or diseases in other members of the household.

(c) REPORT.—Not later than 4 years after the date of enactment of this Act, the Director of the National Institutes of Health shall prepare and submit to the appropriate committees of Congress, a report concerning the results of the study conducted under subsection (a).

SEC. 1914. CONGRESSIONAL APPROPRIATION OF FEDERALLY SUPPORTED DISEASE RESEARCH.

(a) FINDINGS.—Congress finds that—

(1) it is in the public interest to support necessary and valuable biomedical research on diseases and conditions that harm or kill individuals and that threaten public health;

(2) it is in the public interest to allocate scarce Federal taxpayer money for research that is based on scientific merit and cost-effectiveness; and

(3) it is in the public interest for Members of Congress to have a criteria or methodologies to inform and assist them in the decision making process when allocating Federal taxpayer money for specific biomedical research.

(b) STUDY.—

(1) CONTRACT.—The Secretary of Health and Human Services shall, subject to the availability of appropriations and subject to paragraph (2), enter into a contract with a public or nonprofit private entity to develop criteria or methodologies which Members of Congress may use to assist and inform them during consideration of allocations for biomedical research.

(2) INSTITUTE OF MEDICINE.—The Secretary of Health and Human Services shall request the In-

stitute of Medicine of the National Academy of Sciences to enter into the contract under paragraph (1) to conduct the study described in such paragraph. If such Institute declines to conduct the study, the Secretary shall carry out paragraph (1) through another public or nonprofit private entity.

(3) ITEMS.—Items that may be considered in the development of the criteria of methodologies may include, but are not limited to, the following—

(A) the populations affected by, or potentially affected by diseases and conditions that are targets for research;

(B) the incidence and prevalence rates of disease and conditions;

(C) mortality rates of the diseases and conditions;

(D) rates of morbidity, impairment disability, and health status and functional outcomes of the diseases and conditions;

(E) the economic burden of the diseases and conditions including past and projected expenditures on diagnosis and treatment;

(F) other economic and social burdens; and

(G) potential for medical research on specific diseases to assist basic research efforts.

(c) SUBMISSION TO CONGRESS.—Not later than 1 year after the date on which the contract under subsection (b)(1) is signed, the Institutes of Medicine of the National Academy of Sciences shall prepare and submit to the Secretary of Health and Human Services, and the appropriate committees of Congress, a report that includes the recommendations developed under subsection (b). Not later than 90 days after the receipt of such report, the Secretary of Health and Human Services shall submit comments on the recommendations to the appropriate committees of Congress.

(d) COSTS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 1994 and 1995.

TITLE XX—MISCELLANEOUS PROVISIONS

SEC. 2001. DESIGNATION OF SENIOR BIOMEDICAL RESEARCH SERVICE IN HONOR OF SILVIO O. CONTE, AND LIMITATION ON NUMBER OF MEMBERS.

(a) IN GENERAL.—Section 228(a) of the Public Health Service Act (42 U.S.C. 237(a)), as added by sec-

tion 304 of Public Law 101–509, is amended to read as follows:

''(a)(1) There shall be in the Public Health Service a Silvio O. Conte Senior Biomedical Research Service, not to exceed 350 members.

''(2) The authority established in paragraph (1) regarding the number of members in the Silvio O. Conte Senior Biomedical Research Service is in addition to any authority established regarding the number of members in the commissioned Regular Corps, in the Reserve Corps, and in the Senior Executive Service. Such paragraph may not be construed to require that the number of members in the commissioned Regular Corps, in the Reserve Corps, or in the Senior Executive Service be reduced to offset the number of members serving in the Silvio O. Conte Senior Biomedical Research Service (hereafter in this section referred to as the 'Service').''.

(b) CONFORMING AMENDMENT.—Section 228 of the Public Health Service Act (42 U.S.C. 237), as added by section 304 of Public Law 101–509, is amended in the heading for the section by amending the heading to read as follows:

''SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH SERVICE''.

SEC. 2002. TECHNICAL CORRECTIONS.

(a) TITLE III.—Subsection (c) of section 316 of the Public Health Service Act (42 U.S.C. 247a(c)) is repealed.

(b) TITLE IV.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 406—

(A) in subsection (b)(2)(A), by striking ''Veterans' Administration'' each place such term appears and inserting ''Department of Veterans Affairs''; and

(B) in subsection (h)(2)(A)(v), by striking ''Veterans' Administration'' and inserting ''Department of Veterans Affairs'';

(2) in section 408, in subsection (b) (as redesignated by section 501(c)(1)(C) of this Act), by striking ''Veterans' Administration'' and inserting ''Department of Veterans Affairs'';

(3) in section 421(b)(1), by inserting a comma after ''may'';

(4) in section 428(b), in the matter preceding paragraph (1), by striking ''the the'' and inserting ''the'';

(5) in section 430(b)(2)(A)(i), by striking ''Veterans' Administration'' and inserting ''Department of Veterans Affairs'';

(6) in section 439(b), by striking ''Veterans' Administration'' and inserting ''Department of Veterans Affairs'';

(7) in section 442(b)(2)(A), by striking ''Veterans' Administration'' and inserting ''Department of Veterans Affairs'';

(8) in section 464D(b)(2)(A), by striking ''Veterans' Administration'' and inserting ''Department of Veterans Affairs'';

(9) in section 464E—

(A) in subsection (d), in the first sentence, by inserting ''Coordinating'' before ''Committee''; and

(B) in subsection (e), by inserting ''Coordinating'' before ''Committee'' the first place such term appears;

(10) in section 464P(b)(6) (as added by section 123 of Public Law 102-321 (106 Stat. 362)), by striking ''Administration'' and inserting ''Institute'';

(11) in section 466(a)(1)(B), by striking ''Veterans' Administration'' and inserting ''Department of Veterans Affairs'';

(12) in section 480(b)(2)(A), by striking ''Veterans' Administration'' and inserting ''Department of Veterans Affairs'';

(13) in section 485(b)(2)(A), by striking ''Veterans' Administration'' and inserting ''Department of Veterans Affairs'';

(14) in section 487(d)(3), by striking ''section 304(a)(3)'' and inserting ''section 304(a)''; and

(15) in section 496(a), by striking ''Such appropriations,'' and inserting the following: ''Appropriations to carry out the purposes of this title,''.

(c) TITLE XV.—Title XV of the Public Health Service Act is amended—

(1) in section 1501(b) (42 U.S.C. 300k(b)), by striking ''nonprofit''; and

(2) in section 1505(3) (42 U.S.C. 300n–1(3)), by striking ''nonprivate'' and inserting ''private''.

(d) TITLE XXIII.—Part A of title XXIII of the Public Health Service Act (42 U.S.C. 300cc et seq.) is amended—

(1) in section 2304—

(A) in the heading for the section, by striking ''**CLINICAL RESEARCH REVIEW COMMITTEE**'' and inserting ''**RESEARCH ADVISORY COMMITTEE**''; and

(B) in subsection (a), by striking ''AIDS Clinical Research Review Committee'' and inserting ''AIDS Research Advisory Committee'';

(2) in section 2312(a)(2)(A), by striking ''AIDS Clinical Research Review Committee'' and inserting ''AIDS Research Advisory Committee'';

(3) in section 2314(a)(1), in the matter preceding subparagraph (A), by striking ''Clinical Research Review Committee'' and inserting ''AIDS Research Advisory Committee'';

(4) in section 2317(d)(1), by striking ''Clinical Research Review Committee'' and inserting ''AIDS Research Advisory Committee established under section 2304''; and

(5) in section 2318(b)(3), by striking ''Clinical Research Review Committee'' and inserting ''AIDS Research Advisory Committee''.

(e) SECRETARY.—Section 2(c) of the Public Health Service Act (42 U.S.C. 201(c)) is amended by striking ''Health, Education, and Welfare'' and inserting ''Health and Human Services''.

(f) DEPARTMENT.—Section 201 of the Public Health Service Act (42 U.S.C. 202) is amended—

(1) by striking ''Health, Education, and Welfare'' and inserting ''Health and Human Services''; and

(2) by striking ''Surgeon General'' and inserting ''Assistant Secretary for Health''.

(g) DEPARTMENT.—Section 202 of the Public Health Service Act (42 U.S.C. 203) is amended—

(1) by striking ''Surgeon General'' the second and subsequent times that such term appears and inserting ''Secretary''; and

(2) by inserting '', and the Agency for Health Care Policy and Research'' before the first period.

(h) VOLUNTEER SERVICES.—Section 223 of the Public Health Service Act (42 U.S.C. 217b) is amended by striking ''Health, Education, and Welfare'' and inserting ''Health and Human Services''.

SEC. 2003. TECHNICAL CORRECTIONS WITH RESPECT TO THE AGENCY FOR HEALTH CARE POLICY AND RESEARCH.

Title IX of the Public Health Service Act is amended—

(1) in section 904(d) (42 U.S.C. 299a-2(d))—

(A) by striking ''IN GENERAL'' in paragraph (1) and inserting ''ADDITIONAL ASSESSMENTS'';

(B) by redesignating paragraphs (1) and (2) as paragraphs (3) and (4), respectively;

(C) by inserting after the subsection designation the following new paragraphs:

''(1) RECOMMENDATIONS WITH RESPECT TO HEALTH CARE TECHNOLOGY.—The Administrator shall make recommendations to the Secretary with respect to whether specific health care technologies should be reimbursable under federally financed health programs, including recommendations with respect to any conditions and requirements under which any such reimbursements should be made.

''(2) CONSIDERATIONS OF CERTAIN FACTORS.—In making recommendations respecting health care technologies, the Administrator shall consider the safety, efficacy, and effectiveness, and, as appropriate, the appropriate uses of such technologies. The Administrator shall also consider the cost effectiveness of such technologies where cost information is available and reliable.''; and

(D) by adding at the end thereof the following new paragraph:

''(5) CONSULTATIONS.—In carrying out this subsection, the Administrator shall cooperate and consult with the Director of the National Institutes

of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency.''; and

(2) in section 914(a)(2)(C), by striking ''904(c)(2)'' and inserting ''904(d)(2)''.

SEC. 2004. TECHNICAL CORRECTIONS WITH RESPECT TO THE HEALTH PROFESSIONS EDUCATION EXTENSION AMENDMENTS OF 1992.

(a) ASSISTANCE IN COLLECTION OF LOANS.—Subpart I of part A of title VII of the Public Health Service Act is amended—

(1) in section 705(a)(2)—

(A) by inserting ''and'' after the semicolon at the end of subparagraph (G);

(B) by striking subparagraph (H); and

(C) by redesignating subparagraph (I) as subparagraph (H); and

(2) by adding at the end of section 707 the following new subsection:

''(j) SCHOOL COLLECTION ASSISTANCE.—An institution or postgraduate training program attended by a borrower may assist in the collection of any loan of that borrower made under this subpart which becomes delinquent. The institution or postgraduate training program will not be subject to section 809 of the Fair Debt Collection Prac-

tices Act for purposes of assisting in the collection of any such loan.''.

(b) FINANCIAL NEED REQUIREMENT.—Subsection (b) of section 722 is amended—

(1) by inserting ''and'' after the semicolon at the end of paragraph (1);

(2) by striking paragraph (2); and

(3) by redesignating paragraph (3) as paragraph (2).

(c) CENTERS OF EXCELLENCE.—Section 739(i)(2)(C) is amended by adding after the period the following new sentence: ''Health professional schools described in paragraph (2) of subsection (c) are eligible for funding under this subsection.''.

(d) TRAINEESHIPS FOR ADVANCED NURSE EDUCATION.—Subsection (a) of section 830 of the Public Health Service Act is amended to read as follows:

''(a) IN GENERAL.—The Secretary may make grants to public and nonprofit private entities to meet the cost of—

''(1) traineeships for individuals in advanced-degree programs in order to educate the individuals to serve as nurse practitioners, nurse midwives, nurse educators, or public health nurses, or in other

clinical nursing specialities determined by the Secretary to require advanced education; and

''(2) traineeships for nurses in certificate nurse midwifery programs which conform to guidelines established by the Secretary under section 822(b), to educate the nurses to serve as nurse midwives.''.

(e) CERTAIN GENERALLY APPLICABLE PROVISIONS.—Subsection (d) of section 860 of the Public Health Service Act is amended by striking ''821, 822, 830, and 831'' and inserting in lieu thereof ''821, 822, and 827''.

SEC. 2005. BIENNIAL REPORT ON CARCINOGENS.

Section 301(b)(4) of the Public Health Service Act (42 U.S.C. 241(b)(4)) is amended by striking ''an annual'' and inserting in lieu thereof ''a biennial''.

SEC. 2006. MASTER PLAN FOR PHYSICAL INFRASTRUCTURE FOR RESEARCH.

Not later than June 1, 1994, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall present to the Congress a master plan to provide for the replacement or refurbishment of less than adequate buildings, utility equipment and distribution systems (including the resources that provide electrical and other utilities, chilled water, air handling, and other services that the Secretary, acting

through the Director, deems necessary), roads, walkways, parking areas, and grounds that underpin the laboratory and clinical facilities of the National Institutes of Health. Such plan may make recommendations for the undertaking of new projects that are consistent with the objectives of this section, such as encircling the National Institutes of Health Federal enclave with an adequate chilled water conduit.

SEC. 2007. TRANSFER OF PROVISIONS OF TITLE XXVII.

(a) IN GENERAL.—The Public Health Service Act (42 U.S.C. 201 et seq.), as amended by section 101 of Public Law 101–381 and section 304 of Public Law 101–509, is amended—

(1) by transferring sections 2701 through 2714 to title II;

(2) by redesignating such sections as sections 231 through 244, respectively;

(3) by inserting such sections, in the appropriate sequence, after section 228;

(4) by inserting before section 201 the following new heading:

''PART A—ADMINISTRATION''; and

(5) by inserting before section 231 (as redesignated by paragraph (2) of this subsection) the following new heading:

''PART B—MISCELLANEOUS PROVISIONS''.

(b) CONFORMING AMENDMENTS.—The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in the heading for title II, by inserting ''AND MISCELLANEOUS PROVISIONS'' after ''ADMINISTRATION'';

(2) in section 406(a)(2), by striking ''2701'' and inserting ''231'';

(3) in section 465(f), by striking ''2701'' and inserting ''231'';

(4) in section 480(a)(2), by striking ''2701'' and inserting ''231'';

(5) in section 485(a)(2), by striking ''2701'' and inserting ''231'';

(6) in section 497, by striking ''2701'' and inserting ''231'';

(7) in section 505(a)(2), by striking ''2701'' and inserting ''231'';

(8) in section 926(b), by striking ''2711'' each place such term appears and inserting ''241''; and

(9) in title XXVII, by striking the heading for such title.

SEC. 2008. CERTAIN AUTHORIZATION OF APPROPRIATIONS.

Section 399L(a) of the Public Health Service Act (42 U.S.C. 280e-4(a)), as added by Public Law 102-515 (106 Stat. 3376), is amended—

(1) in the first sentence, by striking ''the Secretary'' and all that follows and inserting the following: ''there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1997.''; and

(2) in the second sentence, by striking ''Out of any amounts used'' and inserting ''Of the amounts appropriated under the preceding sentence''.

SEC. 2009. PROHIBITION AGAINST SHARP ADULT SEX SURVEY AND THE AMERICAN TEENAGE SEX SURVEY.

The Secretary of Health and Human Services may not during fiscal year 1993 or any subsequent fiscal year conduct or support the SHARP survey of adult sexual behavior or the American Teenage Study of adolescent sexual behavior. This section becomes effective on the date of enactment of this Act.

SEC. 2010. SUPPORT FOR BIOENGINEERING RESEARCH.

(a) STUDY.—The Secretary of Health and Human Services, acting through the Director of the National In-

stitutes of Health, shall conduct a study for the purpose of—

(1) determining the sources and amounts of public and private funding devoted to basic research in bioengineering, including biomaterials sciences, cellular bioprocessing, tissue and rehabilitation engineering;

(2) evaluating whether that commitment is sufficient to maintain the innovative edge that the United States has in these technologies;

(3) evaluating the role of the National Institutes of Health or any other Federal agency to achieve a greater commitment to innovation in bioengineering; and

(4) evaluating the need for better coordination and collaboration among Federal agencies and between the public and private sectors.

In conducting such study, the Director shall work in conjunction with appropriate organizations and representatives including academics, industry leaders, bioengineering societies, and public agencies.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate, and

the Committee on Energy and Commerce of the House of Representatives, a report containing the findings of the study conducted under subsection (a) together with recommendations concerning the enactment of legislation to implement the results of such study.

SEC. 2011. ADMISSION TO THE UNITED STATES OF ALIENS INFECTED WITH THE AIDS VIRUS.

(a) ADMISSION.—Notwithstanding any other provision of law, regulations or directives concerning the exclusion of aliens on health related grounds, infection with HIV, the human immunodeficiency virus, shall constitute a communicable disease of public health significance for purposes of section 212(a)(1)(A)(i) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(1)(A)(i)).

(b) REPORT REQUIRED.—The President shall submit a report by September 1, 1993, containing—

(1) an assessment of the anticipated costs of the admission to the United States of persons with HIV to public health care programs, including such costs as will be borne by States and municipalities, and private insurers and health care providers;

(2) an estimate of the number and origins of persons infected with HIV likely to seek entry into the United States before December 31, 2003;

(3) an assessment of the effectiveness of the Immigration and Nationality Act in preventing persons entering the United States likely to become a public charge, as well as the ability to enforce this Act with regard to persons infected with potentially costly health conditions including, but not limited to HIV;

(4) the cost implications of refugees entering or likely to enter the United States, who carry the HIV virus;

(5) a comparison of the anticipated public and private health care costs associated with aliens infected with HIV with the costs attributable to the entry of aliens suffering from other health conditions.

(c) HIV TESTING.—Except as otherwise provided in subsection (d) the Attorney General, in consultation with the Secretary of Health and Human Services, shall provide for the testing of aliens for infection with HIV in accordance with the policy in effect on January 1, 1993.

(d) WAIVER AUTHORITY.—Subsection (c) may be waived by the Attorney General, in consultation with the Secretary of Health and Human Services for non-immigrants who, except for the provisions of this Act, would

be admissible to the United States, and who seek admission for 30 days or less for the purpose of—

(1) attending educational or medical conferences;

(2) receiving medical treatment;

(3) visiting close family members;

(4) conducting temporary business activities; or

(5) visiting for pleasure (tourism);

and in addition such non-immigrants may be admitted without questions as to whether they are carriers of the HIV virus, at the discretion of the Attorney General.

(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary of HHS to prescribe regulations concerning communicable diseases of public health significance, other than infection with the human immunodeficiency virus in accordance with section 212(a)(1)(A)(i) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(1)(A)(i)).

SEC. 2012. SENSE OF THE CONGRESS REGARDING ACTION ON A REQUEST FOR CERTAIN WAIVERS UNDER THE MEDICAID PROGRAM.

It is the sense of the Congress that—

(1) the Secretary of Health and Human Services should be commended for her commitment to either approve or deny the application for waivers to

conduct a demonstration project under section 1115(a) of the Social Security Act submitted by the Oregon Department of Human Services on November 13, 1992, (hereafter referred to in this section as the ''application'') by March 19, 1993, and

(2) because the application for waivers has been pending for one and a half years and the Oregon State legislature faces a biennium budget currently under consideration, a decision must be reached by March 19, 1993, in order for the legislature to appropriate the funds necessary to implement the Oregon plan.

SEC. 2013. AUTHORIZATION OF APPROPRIATIONS.

Section 2602 of the Low-Income Home Energy Assistance Act of 1981 (42 U.S.C. 8621) is amended—

(1) in the first sentence of subsection (b), by striking ''1993 and 1994'' and inserting ''1993, 1994, and 1995''; and

(2) in subsection (d), by striking ''in each of the fiscal years 1993 and 1994'' and inserting ''for each of the fiscal years 1993, 1994, and 1995''.

SEC. 2014. VACCINE INJURY COMPENSATION PROGRAM.

Section 2111(a) of the Public Health Service Act (42 U.S.C. 300aa-11(a)) is amended by adding at the end thereof the following new paragraph:

''(10) The Clerk of the United States Claims Court is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.''.

TITLE XXI—EFFECTIVE DATES

SEC. 2101. EFFECTIVE DATES.

Subject to section 155, this Act and the amendments made by this Act take effect upon the date of the enactment of this Act.

Passed the Senate February 18 (legislative day, January 5), 1993.

Attest:

Secretary.

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